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Weinstock et al.

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[54] DEVICE FOR USE IN RIGHT VENTRICULAR PLACEMENT AND METHOD FOR USING SAME

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[22] Filed: Sep. 23, 1994

[51] Int. Cl.^{6} A61N 1/372

[52] U.S. Cl. 606/129; 607/122; 128/772

[58] Field of Search 606/129; 607/116, 607/122, 123; 604/264; 128/772

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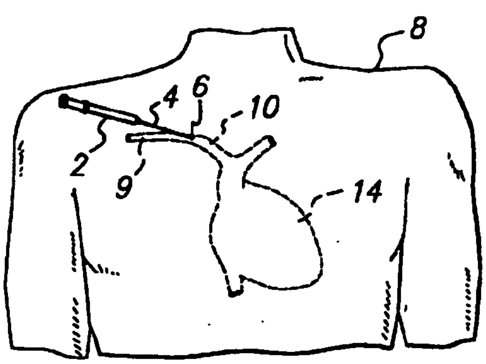
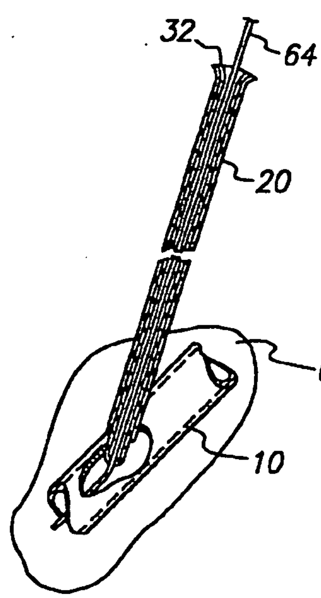
Primary Examiner—Sam Rimell
Assistant Examiner—Benjamin Koo
Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis L.L.P.

[57] ABSTRACT

A device and method for rapid, atraumatic placement of medical devices in the right ventricle of a patient. The device includes an introducer sheath used as a passage for intravenous placement of a medical device in a patient's heart. The introducer sheath is of sufficient length to allow a proximal end thereof to be located outwardly from an incision in the skin of a patient over the cephalic vein when a distal end of the introducer sheath is at the apex of the right ventricle. The introducer sheath is of sufficient flexibility to pass through the tricuspid valve and through the narrow passage between the clavicle and first rib, and is of sufficient strength to allow the introducer sheath to be pushed along its length thereof through the tortuous path from the incision over the cephalic vein to the apex of the right ventricle. The introducer sheath has an inside diameter of sufficient size to slidably receive a balloon-tipped catheter, a guidewire, a pacing lead, or the like therein.

74 Claims, 8 Drawing Sheets





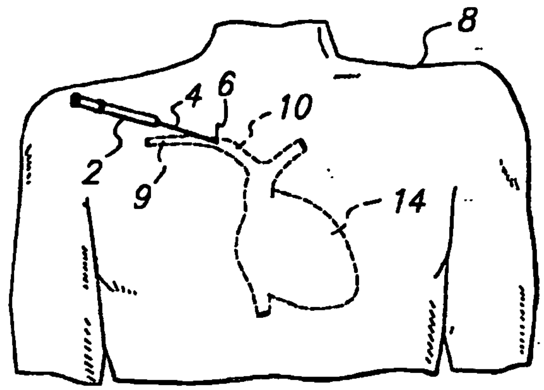


FIG. 1

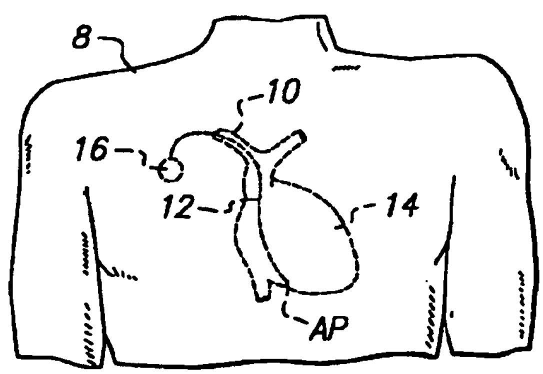


FIG. 2

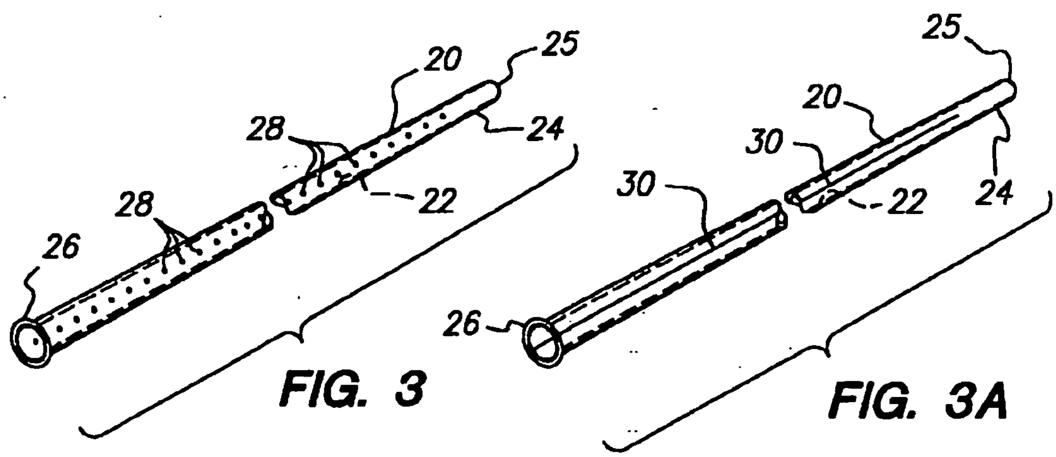


FIG. 3

FIG. 3A

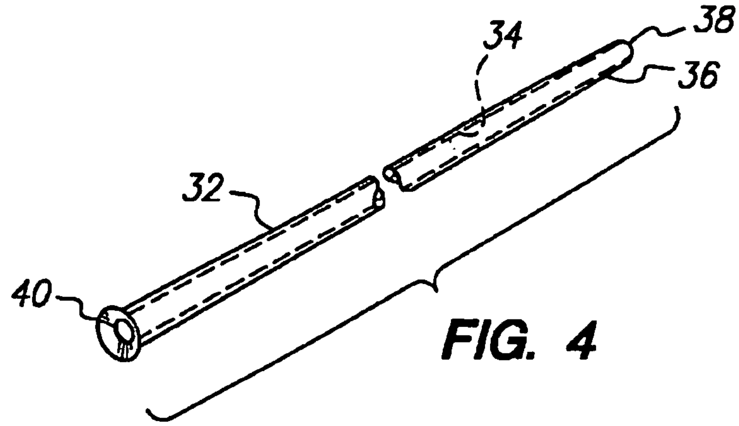


FIG. 4

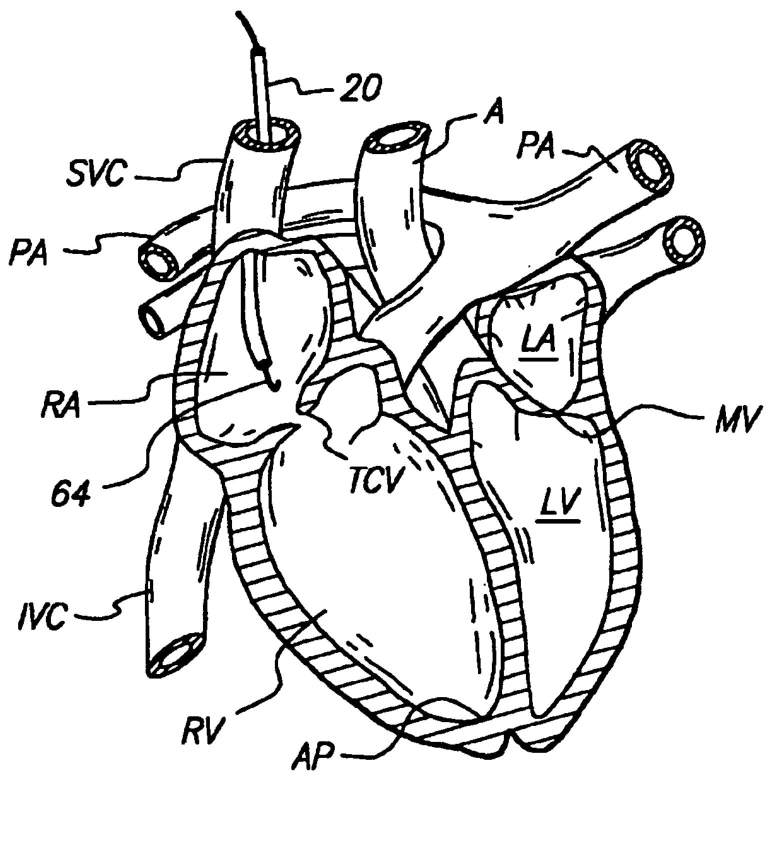


FIG. 11

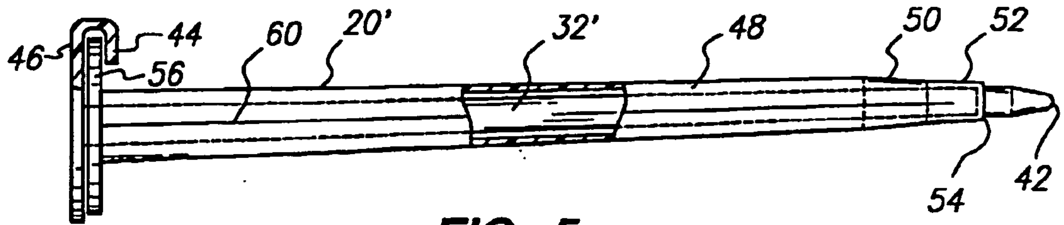


FIG. 5

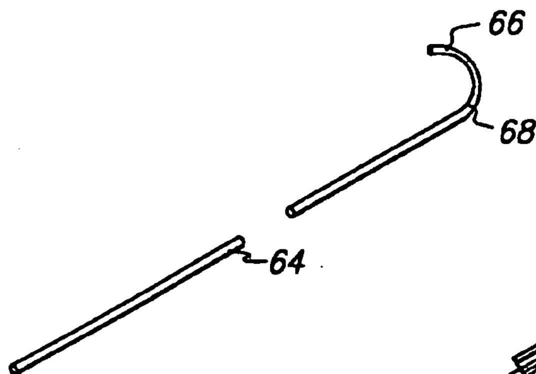


FIG. 6

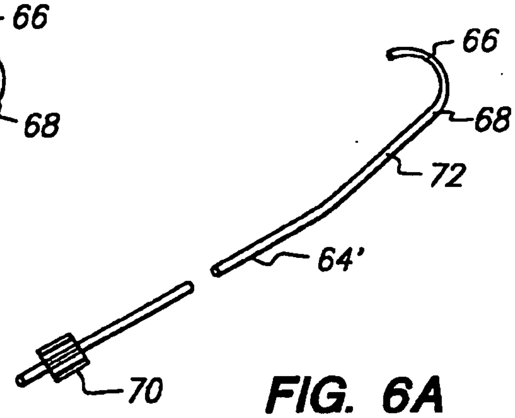


FIG. 6A

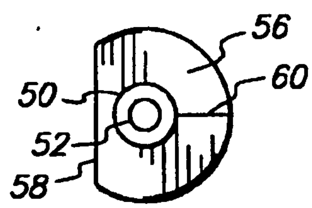


FIG. 5A

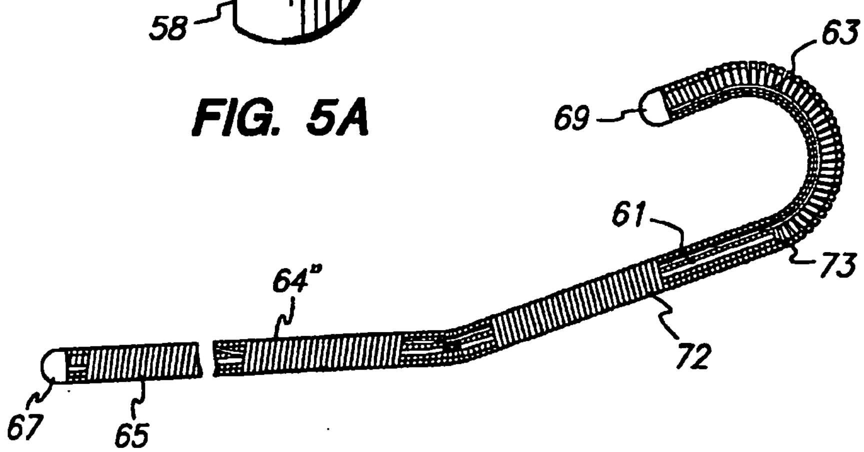


FIG. 6B

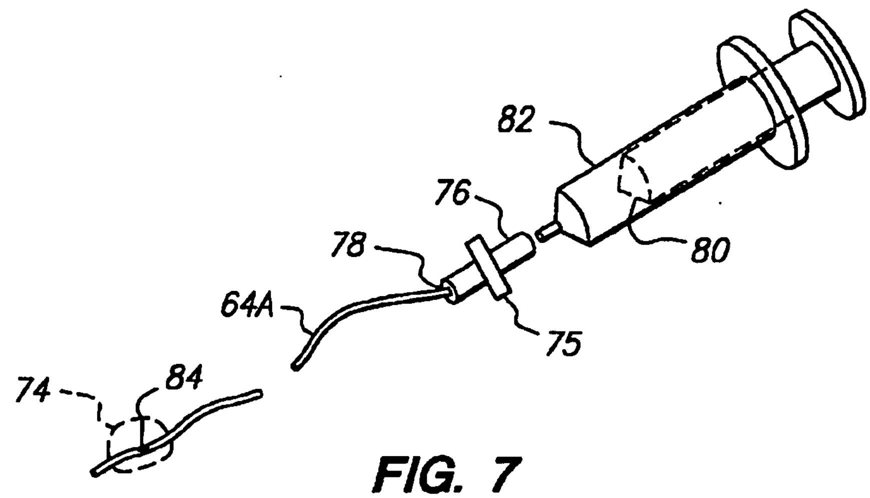


FIG. 7

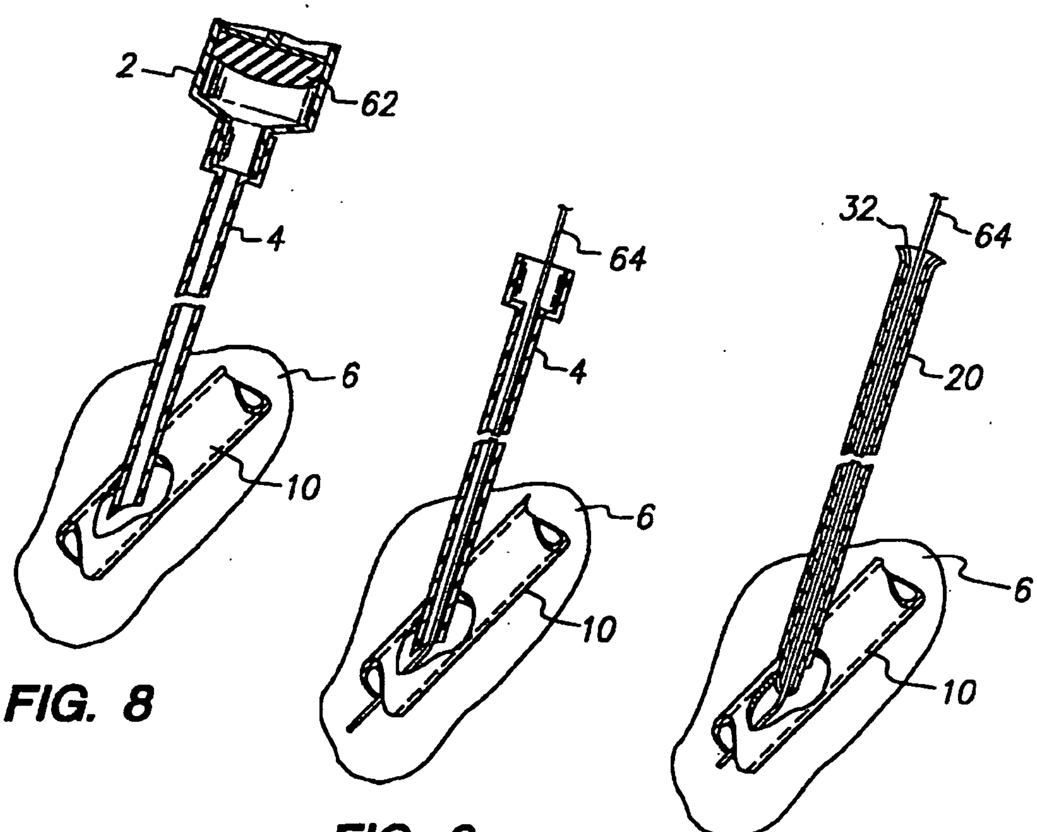


FIG. 8

FIG. 9

FIG. 10

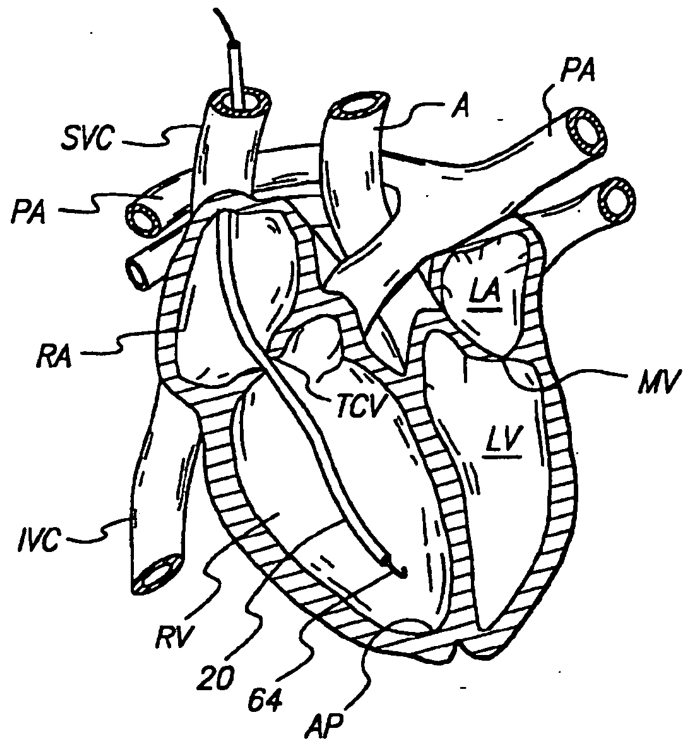


FIG. 12

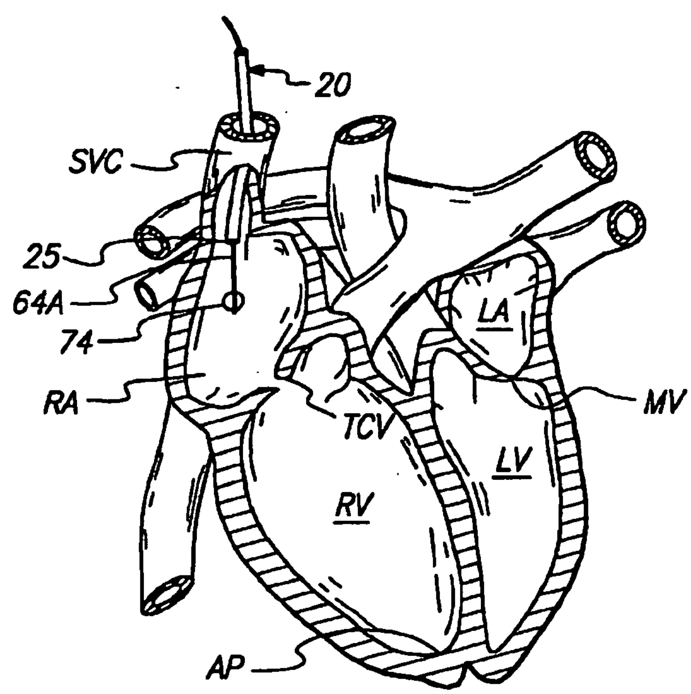
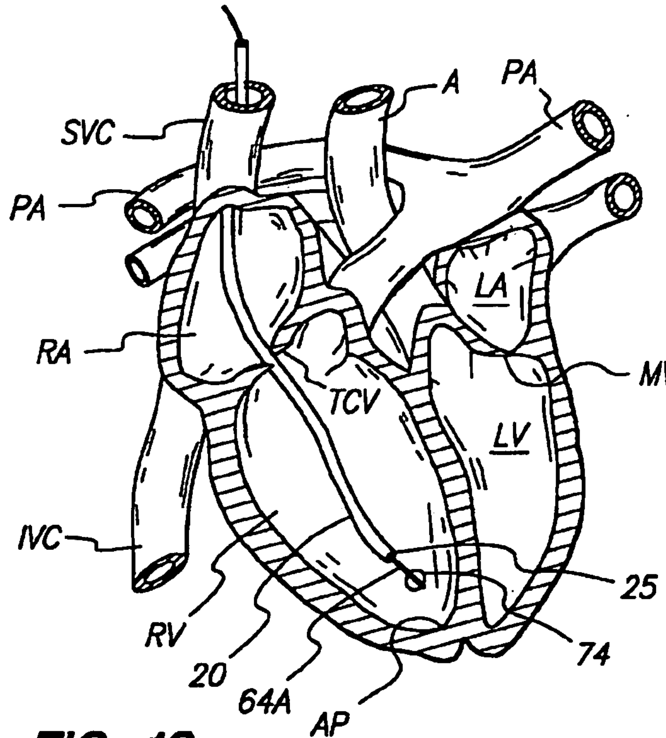


FIG. 12A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74
20
64A
AP

FIG. 13

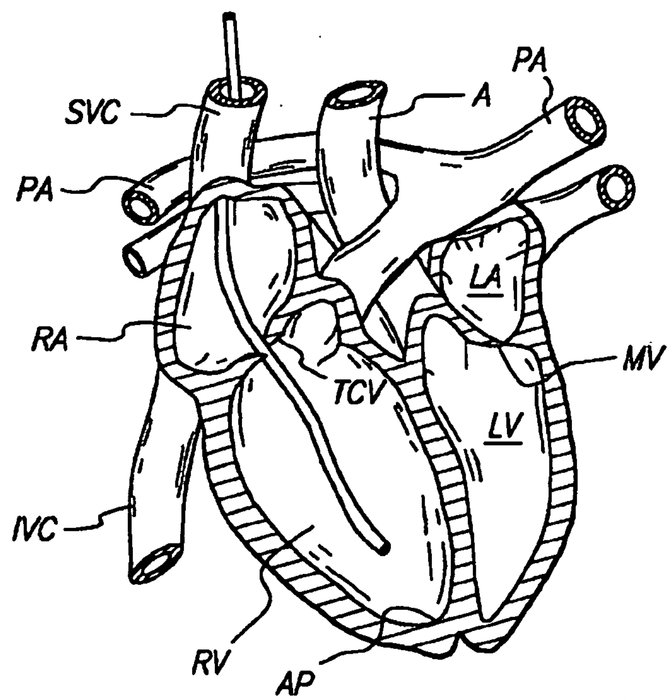
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FIG. 14

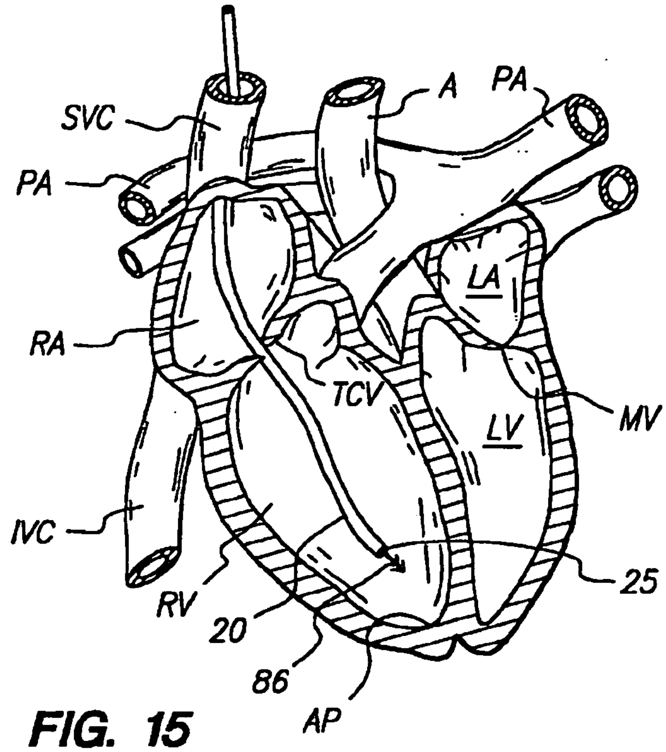
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FIG. 15

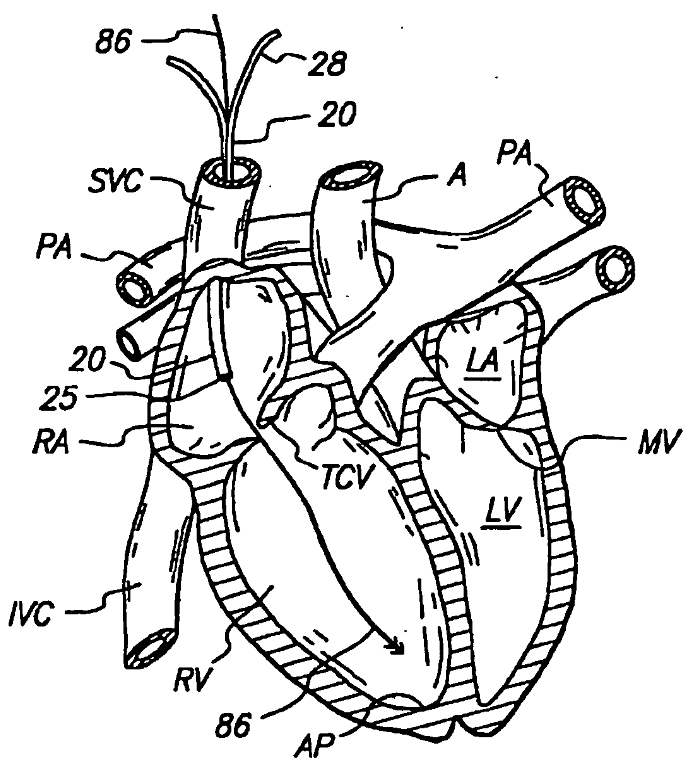
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FIG. 16

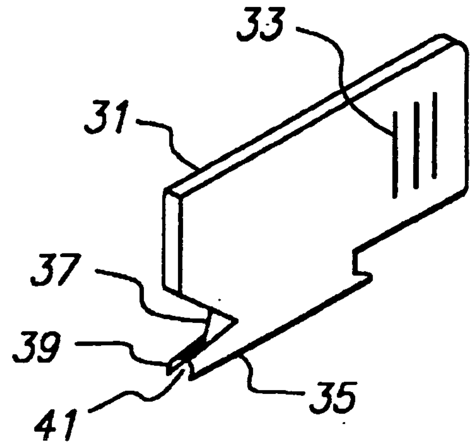

FIG. 17

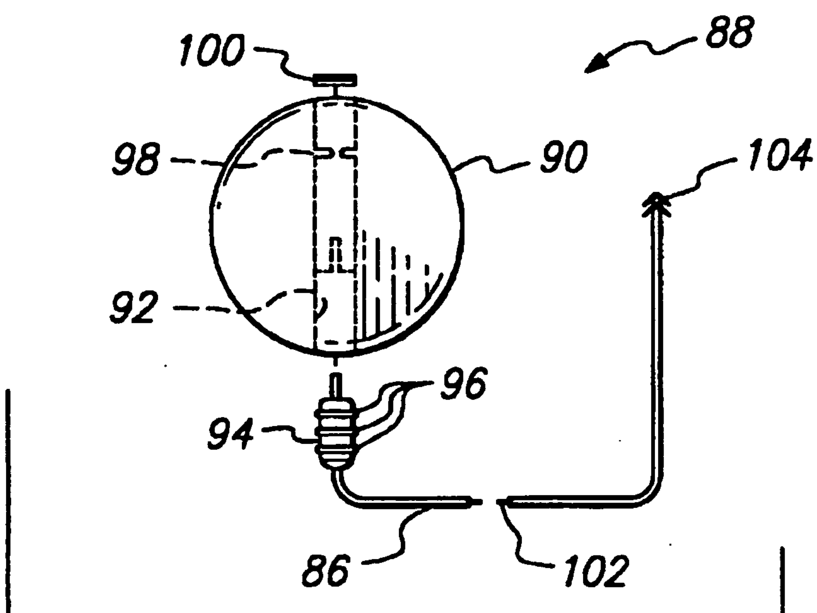

FIG. 18

DEVICE FOR USE IN RIGHT VENTRICULAR PLACEMENT AND METHOD FOR USING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is directed to a device and method especially useful in the insertion of medical devices in the right ventricle of the heart. The invention provides a novel and improved introducer sheath useful in placement of a ventricular pacing lead at the apex of the right ventricle for permanent pacemaker implantation. The present invention also relates to an improved dilator for use with the introducer sheath.

2. Prior Art

Development of permanent implantable pacemaker systems has resulted in life-saving benefits and has greatly improved the quality of life of patients with symptomatic bradyarrhythmias. There are single chamber ventricular pacing methods and dual chamber atrial-ventricular pacing methods. The benefits of dual chamber pacing compared to single chamber ventricular pacing are well documented. Most dual chamber pacing systems use separate atrial and ventricular pacing leads. Permanent pacemaker systems also have been developed which maintain atrial-ventricular synchrony using only a single permanent pacing lead. Such systems are only applicable to specific patient subpopulations. Single chamber atrial pacing is rarely appropriate. Therefore, nearly all patients who undergo permanent pacemaker implantation require ventricular pacing lead placement.

Techniques currently in use for permanent pacemaker implantation typically obtain venous access by one of two methods. A mid infraclavicular incision is made in the skin on either the left or right side of the patient. The left or right subclavian vein is punctured with a thin-walled, large-bore needle and a guidewire is passed into the vein. The needle is removed and an introducer sheath is advanced over the wire with the aid of a dilator into the subclavian vein. After the introducer sheath is in the subclavian vein, the dilator is withdrawn. The pacemaker lead is passed into the venous circulation system through the introducer sheath. The guidewire may be removed or may be left in place as the pacing lead is passed through the system. Current introducer sheaths are only of sufficient length to ensure access to the subclavian vein and, in some patients, to the superior vena cava. Alternatively, a pacemaker lead can be introduced by isolating the cephalic vein and introducing the lead under direct visualization via a venotomy. Regardless of the technique used to obtain venous access, the pacemaker lead must then be advanced via the superior vena cava into the right atrium and then manipulated across the tricuspid valve into the right ventricle and then further advanced past ventricular trabeculae to the apex of the right ventricle for optimal pacing location.

The range of ventricular lead placement devices available for cardiologists and surgeons today are often cumbersome and time consuming to use, especially for cardiologists and surgeons with low annual volumes of pacemaker implantations (i.e. less than 75 pacemaker implants per year). Cardiologists and surgeons frequently have trouble passing the ventricular pacing lead across the tricuspid valve to the apex of the right ventricle because of the interaction of the lead tines or active fixation apparatus with the tricuspid valve or with right ventricle trabeculae. Additionally, the ventricular pacing lead may be inadvertently passed into the coronary sinus. These problems result in increased blood loss and increased radiation exposure for the physician, assistants, and patient.

The present invention is designed to eliminate the problems associated with passing the ventricular pacing lead through the tricuspid valve and past the ventricular trabeculae, prevent inadvertent passing of the pacing lead into the coronary sinus, reduce blood loss, and reduce radiation exposure for the physician, assistants, and patient.

Pacemaker leads are very soft and flexible, thus not easily guided and manipulated into the proper location. Therefore, it is common to use straight and curved stylets to temporarily stiffen the pacing lead and provide directional control to facilitate manipulation of the pacing lead from the right atrium across the tricuspid valve into the right ventricle. Typically, a straight stylet is used to initially introduce the lead into the right atrium. Then the straight stylet is removed and a curved stylet is used to advance the pacing lead across the tricuspid valve into the right ventricle. It is common practice to use the curved stylet to advance the pacing lead past the right ventricle into the right ventricle outflow tract or pulmonary artery to ensure that the pacing lead is not in the coronary sinus. Often times, the curved stylet must be removed and re-shaped during the procedure to attain adequate manipulation and positioning. Then the pacing lead is withdrawn from the right ventricle outflow tract or pulmonary artery using a straight stylet to allow the pacing lead to descend into the apex of the right ventricle for fixation of the pacing lead at the apex with the tines or the active fixation mechanism. Since the coronary sinus does not communicate with the right ventricle outflow tract or pulmonary artery, this technique helps to ensure that the pacing lead is in the right ventricle instead of the coronary sinus. The lead placement procedure is done under fluoroscopy to enable proper pacing lead placement.

The standard method for ventricular pacing lead placement requires extensive lead manipulation, multiple stylet exchanges, and multiple stylet reshapings. In addition, the standard method has potential for inappropriate lead positioning in the coronary sinus and exposing the physician, nurses, and patient to excessive radiation due to the extended use of fluoroscopy.

U.S. Pat. No. 4,243,050 to Littleford discloses a conventional introducer, introducer sleeve and method for implanting pacemaker electrodes in a patient. The introducer and introducer sleeve are dimensioned to only reach into the subclavian vein. Stylets are used inside of the pacing lead in order to advance the lead through the venous system to the apex of the right ventricle.

U.S. Pat. No. 4,467,817 to Harris discloses a small diameter pacing lead of carbon filaments surrounded by a stiffening sheath. The tip of the pacing lead extends beyond the stiffening sheath whereby the stiffening sheath is positioned behind the tip of the pacing lead to assist guiding the pacing lead into the desired organ.

European Patent Application No. 219,608 of Osypka discloses a pacing lead enclosed by a guide sleeve. The guide sleeve is a protective coating that extends over the attaching end of the pacing lead. The guide sleeve has a longitudinal tear line along its length so that it may be separated as it is retracted from the pacing lead.

U.S. Pat. No. 4,602,645 to Barrington et al. discloses a cardiac pacing catheter system used for temporary placement of pacing leads for atrio-ventricular pacing. A standard length introducer sleeve is used to introduce the cardiac pacing catheter system into the subclavian vein. The catheter

containing the pacing leads is advanced through the superior vena cava to the entry to the right atrium and then secured in place. Then the ventricular lead is extended into and through the right atrium, through the tricuspid valve and into the right ventricle. Subsequently, the atrial lead is extended into the right atrium.

U.S. Pat. No. 5,246,014 to Williams et al. discloses a complex implantable active fixation lead system consisting of an active fixation pacing lead, an introducer having a coupler which engages a crank portion on the active fixation pacing lead, and a guide catheter that is assembled with the pacing lead and the introducer for imparting stiffness and improved steerability to the pacing lead. The implantable active fixation lead system is inserted through the subclavian vein into the superior vena cava and into the right ventricle through the tricuspid valve. The introducer and active fixation pacing lead are extended past the guide catheter in the area of the right ventricle apex. The active fixation pacing lead is then cranked into the cardiac tissue by rotating the introducer.

In view of the limitations and complexities of the prior art devices, it would be highly desirable to have an apparatus and method that would facilitate simple, rapid permanent pacemaker ventricular pacing lead placement requiring little or no lead manipulation, eliminate the need for multiple stylets, and decrease the risk of inappropriate lead placement.

SUMMARY OF THE INVENTION

One object of the subject invention is to make permanent pacemaker ventricular pacing lead placement a simple, rapid procedure requiring little or no lead manipulation, eliminate the need for multiple stylets, and decrease the risk of inappropriate lead placement in the coronary sinus while maintaining (or increasing) the safety and rapidity of the procedure.

To accomplish this purpose there is provided an introducer sheath that is of sufficient length to reach from an incision over the cephalic vein on either the right or left side of the patient to the apex of the right ventricle. The introducer sheath can be passed through the tricuspid valve to the apex of the right ventricle over a guidewire or a balloon-tipped catheter. The introducer sheath acts as a guide passage for a pacing lead, a guidewire, a balloon-tipped catheter, etc. The ventricular apex at the lowermost portion of the right ventricle is concave and provides a stable location in which the pacemaker lead will not become dislodged as the heart flexes and pumps repeatedly. The introducer sheath acts as a guide chute for the ventricular lead to prevent interaction of the lead tines with either the tricuspid valve or the right ventricle trabeculae. When the pacemaker lead has been positioned at the apex of the right ventricle, the introducer sheath is removed using peel-away or slitting techniques.

In one aspect of the invention there is provided a device for use in rapid, atraumatic placement of medical devices in a right ventricle of a patient comprising: an introducer sheath used as a passage for intravenous placement of a medical device in a patient's heart, the introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an incision in the skin of the patient over the cephalic vein when a distal end of said introducer sheath is at an apex of the right ventricle, being of sufficient flexibility to pass through a tricuspid valve, and being of sufficient strength to allow the introducer sheath to be pushed along the length thereof through a tortuous path from the mid infraclavicular puncture to the apex of the right ventricle; said introducer sheath having an inside diameter of sufficient size to slidably receive a balloon-tipped catheter therein.

In another aspect of the invention there is provided a device for use in rapid, atraumatic placement of medical devices in a right ventricle of a patient comprising: an introducer sheath used as a passage for intravenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an incision in the skin of the patient over the cephalic vein when a distal end of said introducer sheath is at an apex of the right ventricle, being of sufficient flexibility to pass through a tricuspid valve, and being of sufficient strength to allow the introducer sheath to be pushed along the length thereof through a tortuous path from the mid infraclavicular puncture to the apex of the right ventricle; said introducer sheath having a tapered distal segment and an inside diameter of sufficient size to pass a removable flexible guidewire or pacing lead therethrough.

In yet another aspect of the invention there is provided a kit for rapid, atraumatic right ventricular placement of medical devices comprising: a guide member; an introducer sheath used as a passage for intravenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an incision in the skin of the patient over the cephalic vein when a distal end is at an apex of the right ventricle, being of sufficient flexibility to pass through a tricuspid valve, being of sufficient strength to allow the introducer sheath to be pushed along the length thereof through a tortuous path from the mid infraclavicular puncture to the apex of the right ventricle, and having an inside diameter of sufficient size to pass said guide member therethrough; a dilator having a taper at a distal end, a central bore of sufficient size for passing the guide member therethrough, an outside diameter configured for a close fit of said dilator in said introducer sheath, and having a length greater than the length of the introducer sheath.

In one of its method aspects there is provided a method for rapid, atraumatic right ventricular placement of medical devices across a tricuspid valve to an apex of a right ventricle in the heart of a patient comprising: providing a guide member and a hollow needle having an inside diameter sufficient to pass said guide member; providing an introducer sheath used for intravenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an incision in the skin of the patient over the cephalic vein when a distal end is at an apex of the right ventricle, being of sufficient flexibility to pass through a tricuspid valve, being of sufficient strength to allow the introducer sheath to be pushed along the length thereof through a tortuous path from the mid infraclavicular puncture to the apex of the right ventricle, and having an inside diameter of sufficient size to pass said guide member; making an incision in the skin of the patient; inserting said needle into a vein of the patient; passing said guide member through said needle into the subclavian vein and into a superior vena cava; removing said needle; advancing said guide member across the tricuspid valve to the apex of the right ventricle; and advancing the introducer sheath over said guide member across the tricuspid valve into the vicinity of the apex of the right ventricle.

DESCRIPTION OF THE DRAWING

FIG. 1 is a plan view of a patient with a needle being inserted through the subclavian vein to communicate with the heart of the patient.

FIG. 2 is a plan view of a patient with a completed implant of a pacemaker set.

FIG. 3 is a perspective view of an introducer sheath used to implant a pacing electrode in the patient.

FIG. 3A is a perspective view of an alternate embodiment of the introducer sheath of FIG. 3.

FIG. 4 is a perspective view of one embodiment of a dilator in accordance with the present invention.

FIG. 5 is a plan view of another embodiment of a dilator inserted in an introducer sheath in accordance with the present invention.

FIG. 5A is an end view of the proximal end of the introducer sheath of FIG. 5.

FIG. 6 is a perspective view of a flexible guidewire for use with the present invention.

FIG. 6A is a perspective view of an alternate embodiment of the flexible guidewire of FIG. 6.

FIG. 6B is a plan view of an alternate embodiment of the flexible guidewire of FIG. 6.

FIG. 7 is a perspective view of a balloon-tipped catheter for use with the present invention.

FIG. 8 is a perspective view of a needle puncturing the subclavian vein in accordance with a method of the present invention.

FIG. 9 is a perspective view of a guidewire being introduced through the needle into the subclavian vein.

FIG. 10 is a perspective view of the dilator and introducer sheath of FIGS. 3 and 3A being inserted over the guidewire into the subclavian vein.

FIGS. 11–16 illustrate diagrammatically portions of a patient's heart and the manner in which the present invention is used.

FIG. 17 is a perspective view of a slitter for use with the present invention.

FIG. 18 is a plan view of a pacemaker set having a pacing lead.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With continued reference to the drawing, FIG. 1 illustrates a syringe 2 with a needle 4 being inserted in the patient 8 to obtain access to the subclavian vein 10. The subclavian vein 10 is a large vein and readily receives a permanent pacemaker pacing lead. The insertion of the needle 4 is the first step in the method of implanting a pacemaker electrode with minimal incision to the patient. Typically the needle 4 is inserted at a mid infraclavicular position made on the right side of the patient's chest to obtain access to the right subclavian vein. However, the insertion can be made on the left side of the patient's chest to obtain access to the left subclavian vein. As shown in FIG. 2, the patient 8 has a pacing lead 12 extending through the subclavian vein 10 to the heart 14. A pacemaker set 16 is shown implanted within the patient 8.

Access to the subclavian vein 10 can also be attained by sectioning through the tissue layers of the patient 8 down to the cephalic vein 9. The cephalic vein 9 is located in the deltopectoral groove of the chest wall. The cephalic vein 9 extends beneath the clavicle, running ultimately to the subclavian vein 10. After sectioning through the tissue layers to isolate the cephalic vein 9, an incision is made in the cephalic vein 9 and the pacing lead 12 is inserted through the incision and advanced through the cephalic vein 9 to the subclavian vein 10 and then into the heart 14.

One embodiment of an introducer sheath 20 in accordance with the present invention is shown in FIG. 3. The introducer sheath 20 can be used in either of the methods just described and in a method of inserting the pacing lead 12 into the patient 8 as described later. The introducer sheath 20 has an inside diameter 22, a tapered distal segment 24, and a flared proximal end 26. The distal segment 24 and the proximal end 26 can be straight.

The introducer sheath 20 has sufficient flexibility to pass from an incision in the exterior skin 6 over the cephalic vein 9 of patient 8 through the tortuous path in the venous system to the apex AP of the right ventricle of the patient's heart 14. As will be described in more detail below. The introducer sheath 20 is of sufficient length to reach the apex AP of the right ventricle but, in accordance with safe medical practice, during use the distal end is not advanced into contact with the apex AP of the right ventricle instead the distal end is positioned at a location in the vicinity of the apex AP of the right ventricle so as to prevent damage to or perforation of the heart. Particularly, the introducer sheath 20 is of sufficient flexibility to pass through the tricuspid valve of the heart 14 and the narrow passage between the clavicle and first rib. However, the introducer sheath 20 has sufficient strength to allow it to be pushed along its length thereof through that tortuous path. To achieve the necessary combination of flexibility and strength, particularly at the level of the clavicle and first rib where there is minimal clearance, the introducer sheath is of varied stiffness, being more flexible towards distal end 25 and is more stiff towards proximal end 26. For example, this variation in stiffness can be provided in an introducer sheath wherein the wall thickness or the diameter of the introducer sheath 20 can decrease from the proximal end 26 to the distal end 25 while maintaining a constant inside diameter to effect a gradual transition from proximal stiffness to distal flexibility. The variation in stiffness can be along the entire length of the introducer sheath 20 or along a portion of the length. The transition in stiffness can be gradual or can be incremental in multiple stages or sections. There can be two, three, or more sections with decreasing stiffness. Preferably, the distal end 25 is soft and flexible so as to be atraumatic. Particularly, the portion that extends from the superior vena cava SVC to the apex AP of the right ventricle RV is soft and flexible. The variation in stiffness along the relevant portion of the introducer sheath can be achieved by varying the wall thickness, varying the material, such as a polymer of varying density and stiffness (thus enabling constant wall thickness), varying a polymer or metal composition mixture, imparting varied-properties, such as a varied degree of cross-linking (chemical, radiation, etc.) of a polymer, or by a variety of other means which will be apparent to one of ordinary skill in the art following the teachings herein.

The introducer sheath 20 can be relatively flexible because during the majority of its use it is supported internally by a dilator, guide member, balloon-tipped catheter, pacing lead, etc. If the introducer sheath 20 collapses or kinks during use one of the identified components can be inserted through the introducer sheath 20 to straighten it. Preferably, the introducer sheath 20 is sufficiently flexible or soft at the distal end 25 to prevent inadvertent perforation of the myocardium. The introducer sheath can be made of any suitable material having desired strength, flexibility and/or biocompatability properties. Preferably, the introducer sheath 20 has a low-friction surface such as a polymeric material, a photopolyacrylamide-heparin complex, a polyethylene glycol, a hyaluronic acid, or a polyvinylpyrrolidone material (all available from Bio-metric Systems, Inc., Minneapolis, Minn.).

The inside diameter 22 of the introducer sheath is of sufficient size to slidably receive a number of components, such as dilators, guide members, balloon-tipped catheters, pacing leads, or the like. The introducer sheath acts as a guide passage for these components. Preferably, the inside diameter 22 has a low-friction surface so as to allow the components to pass easily through the introducer sheath. As will be recognized by one of ordinary skill in the art, many polymeric materials and coatings, such as fluorocarbons, will provide the desired lubricousness as well as the surfaces discussed above. The inside diameter 22 typically is constant along the length of the introducer sheath and will range from 2 French (2F) to 14 French (0.66 mm to 3.96 mm) depending on the diameter of the components in use therewith. The wall thickness will typically range from 0.17 mm to 0.25 mm. However, smaller and larger sizes can be used should smaller or larger devices need to be introduced into the right ventricle.

Introducer sheath 20 in accordance with the present invention is of greater length than sheaths previously used for right ventricular placement of pacing leads. Introducer sheath 20 is of sufficient length to allow proximal end 26 to be located outwardly from either a right side or left side incision in the exterior skin 6 of the patient 8 over the cephalic vein 9 when distal end 25 is at the apex AP of the right ventricle in the patient's heart 14. Typically, the length of the introducer sheath will range from 20 cm to 75 cm depending on the size of the patient, the length of the pacing lead, etc. Preferably, the introducer sheath is 40 to 60 cm long.

The introducer sheath 20 can also comprise a plurality of perforations 28 to form a weakened line along the length of the introducer sheath 20 to allow the introducer sheath to be split apart or peeled away in order to remove it from the patient 8. Preferably, the perforations are indentations which do not extend completely through the thickness of the introducer sheath 20 so that air does not flow through them.

In another embodiment of the introducer sheath 20 shown in FIG. 3A, a groove 30 forms the weakened line along the length of the introducer sheath 20. The plurality of perforations 28, groove 30, or other weakening means can be in one or more locations around the circumference of the introducer sheath 20 for enabling the introducer sheath 20 to be severable along the length thereof. The weakening means can take a number of forms such as reduced wall thickness or integral cutting agents such as strings and the like.

As an alternative to or in addition to the groove or plurality of perforations, a slitter 31 shown in FIG. 17 can be used to cut apart the introducer sheath 20. The slitter 31 has a gripping area 33 for holding and guiding the slitter when in use. A frusto-conical portion 35 leads to a blade 37 that is used to split apart the introducer sheath 20. The method of using the slitter, groove, plurality of perforations, or other weakening means will be discussed later.

FIG. 4 is one embodiment of a dilator 32 in accordance with the present invention. The dilator 32 has an inside diameter 34, a taper 36 at a distal end 38, and a flared proximal end 40. The dilator 32 is configured to have an outer diameter that closely fits the inside diameter 22 of introducer sheath 20 when the flared proximal end 40 abuts flared proximal end 26 and the taper 36 extends beyond the tapered distal segment 24 of introducer sheath 20. That is, the outer diameter of the dilator 32 is slightly smaller than the inside diameter of the introducer sheath 20 so that the dilator 32 can slide into the introducer sheath 20 without undue friction between the introducer sheath 20 and the dilator 32. The inside diameter 34 is sufficient for the dilator 32 to pass over a guide member, such as a flexible guidewire having a diameter of 0.66 mm to 0.99 mm. The guidewire can be any conventionally used guidewire.

In another embodiment, the outside diameter of the introducer sheath 20 can be tapered from the proximal end 26 to the distal end 25 or the introducer sheath can have an increasing wall thickness from the distal end 25 to the proximal end 26 to provide greater flexibility along its length near the distal end 25 and greater strength along its length near the proximal end 26. Likewise, the introducer sheath 20 can comprise several sections of varying stiffness, the material can be cross-linked, etc. In yet another embodiment, the outside diameter of the dilator 32 can be tapered from the proximal end 40 to the distal end 38 to closely fit the inside diameter of the introducer sheath 20. The introducer sheath 20 preferably only has increased flexibility along the distal portion extending from the superior vena cava SVC to the apex AP of the right ventricle RV.

FIGS. 5 and 5A illustrate an alternate embodiment of the dilator and introducer sheath. The dilator 32' has a tapered distal end 42 and a central bore (not shown) configured to receive a guide member. The dilator 32' has a clip 44 attached to the proximal end 46, the clip extending in the distal direction and then radially inwardly. The introducer sheath 20' has a first portion 48 having an inside diameter greater than the outside diameter of the dilator 32'. The introducer sheath 20' can be slightly tapered from the distal end of the first portion 48 along tapered segment 50 to a cylindrical portion 52. In the alternative, the introducer sheath 20' can be tapered from the distal end of the first portion 48 all the way to distal end 54. Preferably, the distal end 54 of the introducer sheath 20' is rounded to prevent damage during entry into the subclavian vein 10.

The introducer sheath 20' further includes a flange 56 at its proximal end. The flange 56 can have a flat portion 58 (FIG. 5A) along its periphery corresponding to the shape and size of the clip 44 of the dilator 32'. The clip 44 and flange 56 can be locked together by axially sliding the introducer sheath 20' onto the dilator 32' so that the flat portion 58 passes under the clip 44 and then by rotating the introducer sheath 20' so that flange 56 engages clip 44. This allows the introducer sheath 20' to be detachably mated with the dilator 32' to prevent separation of the introducer sheath and dilator during insertion and manipulation of the two in the patient's body. The introducer sheath 20' can further include a groove or slit 60 extending through the flange 56 along the first portion 48 into the taper 50. The groove or slit 60 through the flange 56 allows the flange 56 to be broken apart so that the introducer sheath 20' can be pulled apart along the groove 60. Preferably, the introducer sheath 20' and dilator 32' are made of a polypropylene material.

FIGS. 8–16 illustrate the methods of inserting the pacing lead 12 into the patient's heart 14. The heart 14 and associated structures include the subclavian vein 10, superior vena cava SVC, inferior vena cava IVC, right atrium RA, tricuspid valve TCV, right ventricle RV, apex AP of the right ventricle, pulmonary artery PA, left ventricle LV, mitral valve MV, left atrium LA, and aorta A.

FIG. 8 shows the needle 4 puncturing the exterior skin 6 of the patient 8 to enter the subclavian vein 10. Preferably, an 18 gauge, thin wall needle is employed in accordance with the present invention. However, the size of the needle can be smaller or larger depending on the size of the components to be used therewith such as a guidewire, etc. A piston 62 of syringe 2 is withdrawn slightly to draw a small

quantity of blood from the subclavian vein 10 to insure that the needle 4 has entered the vein. The syringe 2 is removed from the needle 4. A flexible guide member 64 as illustrated in FIG. 6 or 6A is pushed through the needle 4 to enter the subclavian vein 10 as shown in FIG. 9. Alternatively, the flexible guide member 64 can be advanced into the subclavian vein 10 through the cephalic vein as discussed above.

The flexible guide member 64 can be a straight, J-tipped guidewire as shown in FIG. 6. The guide member 64 is of sufficient diameter to pass through the needle 4. Typically, guidewire diameters range from 2F to 3F (0.66 mm to 0.99 mm). The guide member 64 preferably has a flexible J-tip 66 at a distal end 68. The curved segment extends through an arc of approximately 150° and typically has a radius of 3.0 to 6.0 mm. The J-tip is flexible so that it will flex easily to a straight configuration so as to be easily slidable through the needle 4. However, the curved segment is resiliently biased so that when it exits the needle it assumes its J-shape in a relaxed state. The guide member 64 typically will range in length from 40 cm to 120 cm, but preferably is 100 cm long.

FIG. 6A illustrates an alternative configuration for the guide member. Guide member 64' is an angled, J-tipped guidewire with an angled segment 72. Preferably, the angulation of the guidewire is approximately 135° and occurs at about 4 cm from the J-tip 66 at the distal end 68. A removable torquing or steering device 70 can be attached to guide member 64'. The steering device 70 facilitates rotation of the guide member 64' to orient the angled segment directionally toward the tricuspid valve TCV (FIG. 11).

FIG. 6B illustrates another embodiment for the guide member. The guide member 64" is comprised of three wires. An outer coiled wire 65 extending from proximal end 67 to distal end 69. The wire diameter is typically 0.178 mm and is coiled to form an overall coil diameter ranging from 2F to 3F (0.66 mm to 0.99 mm). The outer coiled wire 65 can be stainless steel, coated with tetrafluoroethylene fluorocarbon polymers such as the one sold under the trade name "TEFLON" (available from E.I. DuPont de Nemours Co., Wilmington, Del., 19898) and/or heparin bonded. Within the coiled wire 65, there is a holding wire 63 attached to the distal end 69 and at a point near the proximal end 67 to minimize the possibility of coil fracture or stretching. The holding wire diameter typically ranges from 0.30 mm to 0.51 mm. Also within the coiled wire 65 is a support wire 61. The desired angled segment 72 can be formed by angling the support wire 61. In addition, the support wire 61 can be a flat, formable wire (i.e., ribbon-type wire 0.254 mm wide and 0.076 mm thick) to help facilitate angulation.

The support wire 61 can be either fixed or movable. The fixed support wire extends from the proximal end 67 to a point 73 at the beginning of the flexible J-tip 66. The fixed support wire typically tapers over its distal-most portion (i.e., approximately the last 6 cm. If the support wire 61 is movable, the location of the angulation is movable as well to accommodate variously shaped hearts. The movable support wire can be coated with tetrafluoroethylene fluorocarbon polymers such as the one sold under the trade name "TEFLON" (available from E.I. DuPont de Nemours Co., Wilmington, Del., 19898) to provide free movement within the outer coiled wire 65. The support wire 61 and holding wire 63 can be stainless steel, coated with tetrafluoroethylene fluorocarbon polymers such as the one sold under the trade name "TEFLON" (available from E.I. DuPont de Nemours Co., Wilmington, Del., 19898), and/or heparin bonded.

The needle 4 is then removed enabling the dilator 32 and introducer sheath 20 to be guided over the guide member 64 to enter the subclavian vein 10 as shown in FIG. 10. The dilator 32 adds mechanical strength to the introducer sheath 20 during entry into the patient 8 through soft tissue and muscle until the dilator 32 and introducer sheath 20 reach the venous system. The dilator 32 is removed after the introducer sheath is sufficiently inserted into the superior vena cava SVC over guide member 64. The dilator 32 and introducer sheath 20 can be guided over the guide member 64 whether the guide member 64 is inserted in the cephalic vein or the subclavian vein.

Typical introducer sheaths are only long enough to be advanced into the superior vena cava SVC. However, the introducer sheath of the present invention can be advanced past the superior vena cava SVC. FIG. 11 shows the introducer sheath 20 advanced over the guide member 64 into the right atrium RA. Preferably, the introducer sheath 20 is advanced through the superior vena cava SVC into the right atrium RA under fluoroscopy.

In many cases, the straight, J-tipped guidewire 64 or angled, J-tipped guidewire 64' can be advanced into the right ventricle RV. The preformed, J-shaped curve on the distal end of the guide member facilitates crossing the tricuspid valve TCV atraumatically. If the guide member 64 or 64' passes easily into the right ventricle RV through the tricuspid valve TCV, the introducer sheath 20 can be advanced over the guide member 64 or 64' into the right ventricle RV as shown in FIG. 12. The introducer sheath 20 is advanced over the guide member 64 or 64' by pushing along the length of the introducer sheath that is located outwardly from the mid infraclavicular puncture in the patient's skin. Once the introducer sheath 20 is positioned in the right ventricle RV in the vicinity of the apex AP, the guide member 64 or 64' can be withdrawn. If preferred, the guide member 64 or 64' can be retained.

If the guide member 64 or 64' does not pass easily through the tricuspid valve TCV, the guide member 64 or 64' is removed and a balloon-tipped, flotation catheter 64A as shown in FIG. 7 is inserted in the introducer sheath 20. The balloon-tipped catheter 64A is typically 40 cm to 95 cm in length and preferably 75 cm. The outside diameter of the balloon-tipped catheter typically ranges from 4F to 8F (1.32 mm to 2.64 mm) and preferably is 5F (1.65 mm).

The balloon-tipped catheter 64A is advanced in a deflated position through the introducer sheath 20 until it exits the distal end 25 of the introducer sheath 20 in the right atrium RA as shown in FIG. 12A. The balloon 74 is inflated after it exits the distal end 25 of the introducer sheath 20 by opening the stop cock 75 of valve 76 attached to the proximal end 78 of the balloon-tipped catheter 64A (FIG. 7) and depressing the piston 80 of syringe 82 which is attached to valve 76. The piston 80 forces air in the syringe 82 through an inflation lumen in the balloon-tipped catheter 64A and into the balloon 74 through opening 84. After inflating the balloon 74, the stop cock 75 is closed so that the balloon 74 remains inflated. The inflated balloon diameter is approximately 1 cm. It will be appreciated by one of ordinary skill in the art that other balloon-tipped catheters commonly known in the art such as double or triple lumen balloon-tipped catheters can be used in accordance with the present invention.

The introducer sheath 20 is stabilized with its distal end 25 in the right atrium RA and the balloon-tipped catheter 64A is advanced under fluoroscopy through the tricuspid valve TCV taking advantage of the flow-directed properties of the inflated balloon 74 to be carried by the blood flow into the right ventricle RV instead of into the inferior vena cava

IVC. The balloon-tipped catheter 64A is advanced to the vicinity of the apex AP of the right ventricle RV. The position of the balloon-tipped catheter 64A can be confirmed fluoroscopically. After stabilizing the position of the balloon-tipped catheter 64A, the introducer sheath 20 is advanced across the tricuspid valve TCV over the balloon-tipped catheter 64A until its distal end 25 is close to or meets the inflated balloon 74 as shown in FIG. 13. Preferably, the balloon 74 is left inflated to prevent advancing the introducer sheath 20 too far and possibly perforating the apical myocardium of the right ventricle RV.

A radio-opaque distal tip marker such as barium sulphate on the introducer sheath 20 can be provided to improve fluoroscopic visualization of the distal end 25 of the introducer sheath 20. Likewise, other radio-opaque markers can be used, or a portion of or the entire length of the introducer sheath can be radio-opaque. In addition, the balloon-tipped catheter 64A can have similar types of radio-opaque markers. Radio-opaque markers along the introducer sheath 20 can be used to measure the proper length of a permanent pacemaker pacing lead. In this way, a pacing lead that is too short or too long won't first be inserted and then have to be removed and replaced with a proper length lead as sometimes occurs with conventional methods.

After stabilizing the introducer sheath 20 in position in the vicinity of the apex AP of the right ventricle RV, the balloon 74 is deflated by opening stop cock 75 and the balloon-tipped catheter 64A is withdrawn and removed from the patient 8 as seen in FIG. 14. After completely removing the balloon-tipped catheter 64A, a permanent ventricular pacing lead 86 is advanced through the introducer sheath 20 directly into the right ventricle RV without the possibility of inadvertently passing into the coronary sinus or becoming entangled in the tricuspid valve TCV or with right ventricle trabeculae (FIG. 15). With the introducer sheath 20 of the present invention advanced through the tricuspid valve TCV, there is no need to use a curved stylet to advance the pacing lead 86 into the right ventricle RV as is usually necessary with conventional introducer sheaths. A straight stylet in the pacing lead 86 is sufficient. The pacing lead 86 can also have sufficient strength itself to pass through the introducer sheath 20 into the right ventricle RV without the need for any stylet.

It is not necessary, and may not be desirable, for the pacing lead 86 to exit from the distal end 25 of the introducer sheath 20. Advancing the pacing lead 86 out the distal end 25 of the introducer sheath 20 increases the risk of perforating the apex AP of the right ventricle RV. Likewise, manipulating the introducer sheath 20 in a forward direction in the vicinity of the apex AP of the right ventricle RV should not be done as damage to the introducer sheath 20 or trauma to the right ventricle RV may occur. The radio-opaque markers could serve to identify how far in a distal direction to advance the pacing lead 86. In addition, if re-positioning of the introducer sheath 20 is desired, the balloon-tipped catheter 64A can be reinserted and advanced to the apex AP of the right ventricle RV so that the introducer sheath 20 can be advanced over the body of the balloon-tipped catheter 64A.

When the pacing lead 86 has been positioned near the apex AP of the right ventricle so as to achieve adequate pacing and sensing, the introducer sheath 20 is withdrawn and removed from the patient 8. The introducer sheath 20 is withdrawn and removed from the pacing lead 86 by sliding the introducer sheath 20 proximally over the pacing lead 86 and splitting apart the introducer sheath 20 along the plurality of perforations 28, groove 30, or whatever weakening means exists as shown in FIG. 16.

Because of the length of the introducer sheath 20 and the need for the position of the pacing lead 86 to remain stable, optimal introducer sheath 20 removal may require a scalpel-like, slitter 31 as shown in FIG. 17 and described above. Channel 41 of frusto-conical portion 35 can be attached to the body of the pacing lead 86 to facilitate slitting of the introducer sheath 20 during withdrawal of the introducer sheath 20. The frustum 39 is inserted into the introducer sheath 20 and the introducer sheath 20 is pulled proximally over the frusto-conical portion 35 to engage the scalpel-like blade 37. The blade 37 cuts the introducer sheath 20 and the conical shape of the frusto-conical portion 35 helps to separate the introducer sheath 20 as it is pulled proximally. Gripping area 33 helps to stabilize the slitter 31 during use.

After the introducer sheath 20 is completely removed from the patient 8, the pacing lead 86 is connected to a pacing systems analyzer and standard evaluation of lead position can be performed by testing pacing thresholds, sensing, and lead impedance. Minor position changes can be accomplished by manipulating the pacing lead 86 directly if necessary. After the pacing lead 86 is properly positioned, the permanent pacemaker set 88 is then attached and implanted in the patient 8 using standard pacemaker procedures.

The pacing lead 86 can be part of a permanent pacemaker set 88 such as the one that is illustrated in FIG. 18. Typically, pacing leads have a diameter of 4F to 11F (1.32 mm to 3.63 mm). However, the present invention could be down-sized to accommodate the placement of smaller diameter leads. The pacemaker set 88 has a pulse generator 90 comprising an electronic circuit and power supply encapsulated therein. The pulse generator 90 has a receptacle 92 for receiving a plug 94 of the pacing lead 86. The plug 94 has a plurality of ridges 96 which operate as O-rings to form a seal with the receptacle 92 when the plug 94 is inserted therein. The plug 94 is secured in the pulse generator 90 with vice screw 98. A cap 100 covers the end of the receptacle 92. A conductor 102 connects the plug 94 to a tined pacing lead tip 104. The tined leads are used to attach the pacing lead 86 to the tissue at the apex AP of the right ventricle RV.

Although a specific example of the permanent pacemaker set is described, it will be appreciated by one of ordinary skill in the art that the apparatus and method herein disclosed are not limited to such a pacemaker set. For example, the invention is compatible for use with multiple leads, temporary pacemaker lead placement, an integral or one-piece pulse generator and pacing lead or an active fixation lead can be used in place of the tined lead. It will also be appreciated by one of ordinary skill in the art that all dimensions for guidewires, dilators, sheaths, etc. are for example only and that the size of all components can be increased or decreased to fit specific needs.

Although the invention as described pertains to the introduction of permanent pacing leads into the right ventricle RV of the heart 14, other devices can be introduced into the right ventricle RV. Examples of other medical devices include, but are not limited to, leads for implantable defibrillation and/or anti-tachycardia pacing systems, temporary pacing leads, electrophysiology catheters, and mechanical devices such as bioptomes (biopsy forceps) used for performing right ventricular endomyocardial biopsies.

Modifications and variations of the present invention will be apparent to those having ordinary skill in the art having read the above teachings, and the present invention is thus limited only by the spirit and scope of the following claims.

What is claimed is:

1. A device for use in rapid, atraumatic placement of medical devices in a right ventricle of a patient comprising:

an introducer sheath used as a passage for transvenous placement of a medical device in a patient's heart, the introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an opening in the skin of the patient over the cephalic vein when a distal end of said introducer sheath is at an apex of the right ventricle, said introducer sheath having a gradient of stiffness which decreases toward the distal end so as to be sufficiently soft and flexible distally to pass atraumatically through a tricuspid valve and have sufficient strength proximally to allow the introducer sheath to be pushed along the length thereof through a tortuous venous path to the apex of the right ventricle;

said introducer sheath having an inside diameter of sufficient size to slidably receive a balloon-tipped catheter or pacing lead therethrough.

2. The device of claim 1 further comprising:

a balloon-tipped catheter within said introducer sheath.

3. The device of claim 1 further comprising:

a radio opaque marker at the distal end of said introducer sheath.

4. The device of claim 1 further comprising:

at least one radio opaque marker spaced from the distal end of said introducer sheath.

5. The device of claim 1 wherein said introducer sheath is radio opaque along at least a portion of its length.

6. The device of claim 1 further comprising:

a groove extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be split apart.

7. The device of claim 1 further comprising:

a plurality of perforations extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be peeled away.

8. The device of claim 1 further comprising:

a flange attached to the proximal end of said introducer sheath.

9. The device of claim 8 further comprising:

a dilator having a tapered distal end, a central bore of sufficient size to pass a guide member therethrough, and being of sufficient length to extend from a proximal end located at a point beyond said proximal end of said introducer sheath past the distal end of said introducer sheath;

said introducer sheath having an inside diameter configured for a close fit of said dilator in said introducer sheath.

10. The device of claim 9 further comprising:

a clip attached to the proximal end of said dilator for detachably mating with said flange attached to the proximal end of said introducer sheath to prevent separation of said dilator and introducer sheath during manipulation.

11. The device of claim 10 further comprising:

a slitter for slitting said introducer sheath longitudinally from the proximal end to the distal end upon withdrawal of said introducer sheath from the patient.

12. The device of claim 9 wherein the gradient of stiffness comprises one of the following: a wall thickness of the introducer sheath which decreases from the proximal end to the distal end; a wall thickness of the introducer sheath which decreases along at least a portion of its length; an outside diameter of the introducer sheath which decreases from the proximal end to the distal end while the inside diameter of the introducer sheath remains constant; an outside diameter of the introducer sheath which decreases along at least a portion of its length while the inside diameter of the introducer sheath remains constant; stiffness which varies along the length of the introducer sheath from the proximal end to the distal end; stiffness which varies along at least a portion of the introducer sheath; stiffness which varies gradually; stiffness which varies in one incremental step; stiffness which varies in a plurality of steps; a material of varying density; a material of varying polymer or metal composition mixture; and a material having a varied degree of cross-linking.

13. The device of claim 12 wherein the dilator varies in stiffness along at least a portion of its length.

14. The device of claim 1 wherein said length of said introducer sheath is at least 40 cm.

15. The device of claim 1 wherein the inside of said introducer sheath is a low-friction surface.

16. The device of claim 1 wherein said inside diameter of said introducer sheath is at least 1.65 mm.

17. The device of claim 1 wherein said introducer sheath has a length sufficient to extend from the apex of the right ventricle to outwardly of an incision over the cephalic vein on the patient's right side.

18. The device of claim 1 wherein said introducer sheath has a length sufficient to extend from the apex of the right ventricle to outwardly of an incision over the cephalic vein on the patient's left side.

19. The device of claim 1 wherein a distal portion of the introducer sheath that extends from the superior vena cava to an area in the vicinity of the apex of the right ventricle is soft and flexible.

20. A device for use in rapid, atraumatic placement of medical devices in a right ventricle of a patient comprising:

an introducer sheath used as a passage for transvenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an opening in the skin of the patient over the cephalic vein when a soft and flexible distal end of said introducer sheath is at an apex of the right ventricle, said introducer sheath having sufficient flexibility to pass atraumatically through a tricuspid valve and having sufficient strength to allow the introducer sheath to be pushed along the length thereof through a tortuous venous path to the apex of the right ventricle;

said introducer sheath having a gradient of stiffness which decreases toward the distal end along at least a portion of its length and an inside diameter of sufficient size to pass a removable flexible guidewire therethrough.

21. The device of claim 20 further comprising:

a removable flexible guidewire slidably received in said introducer sheath.

22. The device of claim 21 wherein said removable flexible guidewire is an angled, J-tipped guidewire.

23. The device of claim 20 further comprising:

a radio opaque marker at the distal end of said introducer sheath.

24. The device of claim 20 further comprising:

at least one radio opaque marker spaced from the distal end of said introducer sheath.

25. The device of claim 20 wherein said introducer sheath is radio opaque along at least a portion of its length.

26. The device of claim 20 further comprising:

a groove extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be split apart.

27. The device of claim 20 further comprising:

a plurality of perforations extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be peeled away.

28. The device of claim 20 further comprising:

a flange attached to the proximal end of said introducer sheath.

29. The device of claim 28 further comprising:

a dilator having a tapered distal end, a central bore of sufficient size to pass said guidewire therethrough, and being of sufficient length to extend from a proximal end located at a point beyond said proximal end of said introducer sheath past the distal end of said introducer sheath;

said introducer sheath having an inside diameter configured for a close fit of said dilator in said introducer sheath.

30. The device of claim 29 further comprising: a clip attached to the proximal end of said dilator for detachably mating with said flange attached to the proximal end of said introducer sheath to prevent separation of said dilator and introducer sheath during manipulation.

31. The device of claim 29 further comprising:

a slitter for slitting said introducer sheath longitudinally from the proximal end to the distal end upon withdrawal of said introducer sheath from the patient.

32. The device of claim 29 wherein the dilator varies in stiffness along at least a portion of its length.

33. The device of claim 20 wherein said length of said introducer sheath is at least 40 cm.

34. The device of claim 20 wherein the inside of said introducer sheath is a low-friction surface.

35. The device of claim 20 wherein said inside diameter of said introducer sheath is at least 0.66 mm.

36. The device of claim 20 wherein said introducer sheath has a length sufficient to extend from the apex of the right ventricle to outwardly of an incision over the cephalic vein on the patient's right side.

37. The device of claim 20 wherein said introducer sheath has a length sufficient to extend from the apex of the right ventricle to outwardly of an incision over the cephalic vein on the patient's left side.

38. The device of claim 20 wherein the varying stiffness comprises one of the following: a wall thickness of the introducer sheath which decreases from the proximal end to the distal end; an outside diameter of the introducer sheath which decreases from the proximal end to the distal end while the inside diameter of the introducer sheath remains constant; stiffness which varies gradually; stiffness which varies in one incremental step; stiffness which varies in a plurality of steps; a material of varying density; a material of varying polymer or metal composition mixture; and a material having a varied degree of cross-linking.

39. The device of claim 20 wherein a distal portion of the introducer sheath that extends from the superior vena cava to an area in the vicinity of the apex of the right ventricle is soft and flexible.

40. A kit for rapid, atraumatic right ventricular placement of medical devices comprising:

a guide member;

a dilator having a tapered distal end and a central bore of sufficient size for passing the guide member therethrough; and

an introducer sheath used as a passage for transvenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an opening in the skin of the patient over the cephalic vein when a distal end is at an apex of the right ventricle, said introducer sheath having a gradient of stiffness which decreases toward the distal end so as to be sufficiently soft and flexible distally to pass atraumatically through a tricuspid valve and have sufficient strength proximally to allow the introducer sheath to be pushed along the length thereof through a tortuous venous path to the apex of the right ventricle, and having an inside diameter configured for a close fit of said dilator therein;

said dilator having a length greater than the length of the introducer sheath.

41. The kit of claim 40 further comprising:

a flange on the proximal end of said introducer sheath; and

a clip attached to a proximal end of said dilator for detachably mating with said flange of said introducer sheath to prevent separation of said dilator and introducer sheath during manipulation.

42. The kit of claim 41 further comprising a balloon-tipped catheter sized to fit within said introducer sheath.

43. The kit of claim 41 further comprising:

at least one radio opaque marker spaced from the distal end of said introducer sheath.

44. The kit of claim 40 wherein said guide member is a flexible guidewire.

45. The kit of claim 44 wherein said flexible guidewire is angled and J-tipped.

46. The kit of claim 40 further comprising a hollow needle having an inside diameter sufficient to pass said guide member therethrough.

47. The kit of claim 40 further comprising a permanent pacemaker set.

48. The kit of claim 40 further comprising:

a radio opaque marker at the distal end of said introducer sheath.

49. The kit of claim 40 wherein said introducer sheath is radio opaque along at least a portion of its length.

50. The kit of claim 40 further comprising:

a groove extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be split apart.

51. The kit of claim 40 further comprising:

a plurality of perforations extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be peeled away.

52. The kit of claim 40 further comprising:

a slitter for slitting said introducer sheath longitudinally from the proximal end to the distal end upon withdrawal of said introducer sheath from the patient.

53. The kit of claim 40 wherein the gradient of stiffness comprises one of the following: a wall thickness of the introducer sheath which decreases from the proximal end to the distal end; a wall thickness of the introducer sheath which decreases along at least a portion of its length; an outside diameter of the introducer sheath which decreases from the proximal end to the distal end while the inside diameter of the introducer sheath remains constant; an outside diameter of the introducer sheath which decreases along at least a portion of its length while the inside diameter of the introducer sheath remains constant; stiffness which varies along the length of the introducer sheath from the

proximal end to the distal end; stiffness which varies along at least a portion of the introducer sheath; stiffness which varies gradually; stiffness which varies in one incremental step; stiffness which varies in a plurality of steps; a material of varying density; a material of varying polymer or metal composition mixture; and a material having a varied degree of cross-linking.

54. The kit of claim 40 wherein the dilator varies in stiffness along at least a portion of its length.

55. The kit of claim 40 wherein said guide member is a balloon-tipped catheter sized to fit within said introducer sheath.

56. The kit of claim 40 further comprising a flexible guidewire.

57. The kit of claim 56 wherein said flexible guidewire is angled and J-tipped.

58. The kit of claim 40 wherein a distal portion of the introducer sheath that extends from the superior vena cava to an area in the vicinity of the apex of the right ventricle is soft and flexible.

59. A method for rapid, atraumatic right ventricular placement of medical devices across a tricuspid valve to an apex of a right ventricle in the heart of a patient comprising:

providing a guide member and a hollow needle having an inside diameter sufficient to pass said guide member therethrough;

providing an introducer sheath used for transvenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an opening in the skin of the patient over the cephalic vein when a distal end is at an apex of the right ventricle, said introducer sheath having a gradient of stiffness which decreases toward the distal end so as to be sufficiently soft and flexible distally to pass atraumatically through a tricuspid valve and have sufficient strength proximally to allow the introducer sheath to be pushed along the length thereof through a tortuous venous path to the apex of the right ventricle, and having an inside diameter of sufficient size to pass said guide member therethrough;

inserting said needle into a vein of the patient;

passing said guide member through said needle into the vein and into a superior vena cava;

removing said needle;

advancing said guide member across the tricuspid valve to a vicinity of the apex of the right ventricle; and

advancing the introducer sheath over said guide member across the tricuspid valve into the vicinity of the apex of the right ventricle.

60. The method of claim 59 wherein said vein is a cephalic vein.

61. The method of claim 59 wherein said vein is a subclavian vein.

62. The method of claim 59 wherein said guide member is a flexible guidewire.

63. The method of claim 62 further comprising removing said flexible guidewire.

64. The method of claim 63 wherein said flexible guidewire is angled and J-tipped.

65. The method of claim 59 wherein:

said guide member comprises a balloon-tipped catheter;

said method further comprises:

advancing said balloon-tipped catheter in said introducer sheath until a distal end of said balloon-tipped catheter exits the distal end of said introducer sheath in proximity to the tricuspid valve;

inflating a balloon on the distal end of said balloon-tipped catheter;

advancing said balloon-tipped catheter across the tricuspid valve to the apex of the right ventricle; and

advancing said introducer sheath over said balloon-tipped catheter across the tricuspid valve into the vicinity of the apex of the right ventricle and deflating said balloon.

66. The method of claim 59 further comprising:

providing a dilator having a taper at a distal end, a central bore of sufficient size for passing the guide member therethrough, an outside diameter configured for a close fit of said dilator in said introducer sheath, and having a length greater than the length of said introducer sheath;

positioning said dilator fully in said introducer sheath so that the taper at the distal end of said dilator extends past said distal end of said introducer sheath;

sliding said dilator and said introducer sheath together over said guide member through the subclavian vein into the superior vena cava; and

removing said dilator from the superior vena cava.

67. The method of claim 59 further comprising:

providing a permanent pacemaker set having a ventricular pacing lead;

inserting said ventricular pacing lead into said introducer sheath;

advancing said ventricular pacing lead through said introducer sheath to the distal end of said introducer sheath;

removing said introducer sheath;

attaching said ventricular pacing lead to the apex of the right ventricle;

connecting said ventricular pacing lead to said permanent pacemaker set; and

implanting said permanent pacemaker set into the patient.

68. The method of claim 67 wherein:

said introducer sheath further comprises a groove extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be split apart; and the method further comprising removing said introducer sheath by withdrawing said introducer sheath over said ventricular pacing lead and splitting said introducer sheath apart along said groove.

69. The method of claim 67 wherein:

said introducer sheath further comprises a plurality of perforations extending along said introducer sheath to weaken said introducer sheath to allow said introducer sheath to be peeled away; and the method further comprising, removing said introducer sheath by withdrawing said introducer sheath over said ventricular pacing lead and peeling said introducer sheath apart along said perforations.

70. The method of claim 67 further comprising:

providing a slitter for slitting said introducer sheath longitudinally from the proximal end to the distal end upon withdrawal of said introducer sheath from the patient; and the method further comprising, removing said introducer sheath by withdrawing said introducer sheath over said ventricular pacing lead and slitting said introducer sheath apart with the slitter.

71. The method of claim 59 wherein said needle is inserted into the vein on the patient's right side.

72. The method of claim 59 wherein said needle is inserted into the vein on the patient's left side.

73. The method of claim 59 further comprising:

making an incision in the skin of the patient; and

inserting the needle through the incision and into the vein of the patient.

74. A method for rapid, atraumatic right ventricular placement of medical devices across a tricuspid valve to an apex of a right ventricle in the heart of a patient comprising:

providing a balloon-tipped catheter and a hollow needle having an inside diameter sufficient to pass said balloon-tipped catheter therethrough;

providing an introducer sheath used for transvenous placement of a medical device in a patient's heart, said introducer sheath being of sufficient length to allow a proximal end thereof to be located outwardly from an opening in the skin of the patient over the cephalic vein when a distal end is at an apex of the right ventricle, said introducer sheath having a gradient of stiffness which decreases toward the distal end so as to be sufficiently soft and flexible distally to pass atraumatically through a tricuspid valve and have sufficient strength proximally to allow the introducer sheath to be pushed along the length thereof through a tortuous venous path to the apex of the right ventricle, and having an inside diameter of sufficient size to pass said balloon-tipped catheter therethrough;

inserting said needle into a vein of the patient;

passing said balloon-tipped catheter through said needle into the vein and into a superior vena cava;

removing said needle;

advancing said balloon-tipped catheter in said introducer sheath until a distal end of said balloon-tipped catheter exits the distal end of said introducer sheath in proximity to the tricuspid valve;

inflating a balloon on the distal end of said balloon-tipped catheter;

advancing said balloon-tipped catheter across the tricuspid valve to a vicinity of the apex of the right ventricle;

advancing said introducer sheath over said balloon-tipped catheter across the tricuspid valve into a position adjacent the inflated balloon;

deflating said balloon; and

withdrawing the balloon-tipped catheter.

* * * * *

US005931818A

United States Patent [19]

Werp et al.

[11] **Patent Number: 5,931,818**

[45] **Date of Patent: Aug. 3, 1999**

[54] **METHOD OF AND APPARATUS FOR INTRAPARENCHYMAL POSITIONING OF MEDICAL DEVICES**

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[73] Assignee: **Stereotaxis, Inc.**, St. Louis, Mo.

[21] Appl. No.: **08/969,165**

[22] Filed: **Nov. 12, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/920,446, Aug. 29, 1997.

[51] **Int. Cl.**^{6} **A61M 31/00**

[52] **U.S. Cl.** **604/270**; 604/164; 600/434

[58] **Field of Search** 604/95, 164, 170, 604/270; 128/899; 600/434; 606/108

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Primary Examiner—Michael Buiz

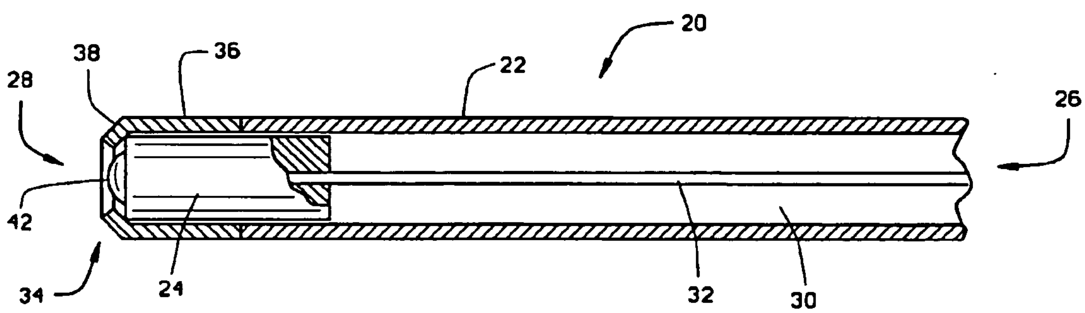
Assistant Examiner—Julian W. Woo

Attorney, Agent, or Firm—Howell & Haferkamp, L.C.

[57] **ABSTRACT**

A catheter and magnet combination adapted for intraparenchymal positioning of the catheter in the body with a magnetic field. The catheter has a proximal and distal ends and a lumen therebetween. A magnet is disposed in the distal end of the lumen so that the distal end of the catheter can be positioned within the body with the aid of an externally applied magnetic field. A tether is attached to the magnet and extends through the lumen and out the proximal end so that the magnet can be removed from the catheter through the lumen once the distal end of the catheter is properly positioned. In one embodiment of the invention, the tether is sufficiently stiff to be able to push the catheter through the tissue. With this embodiment, the magnetic field orients the magnet and thus the tip of the catheter, and some or all of the force for moving the catheter is applied via the tether.

18 Claims, 3 Drawing Sheets



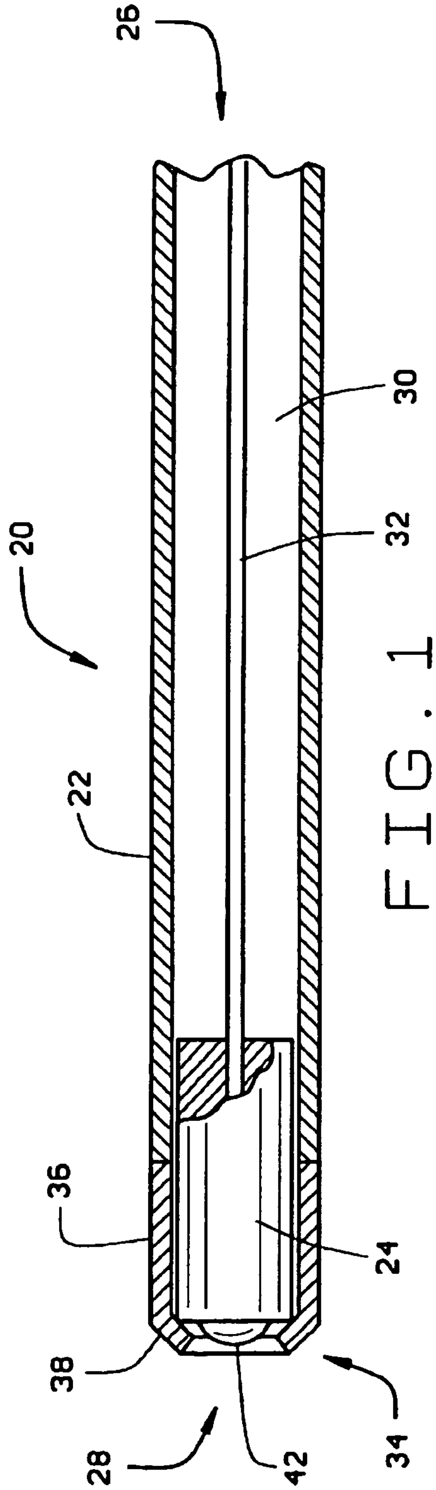


FIG. 1

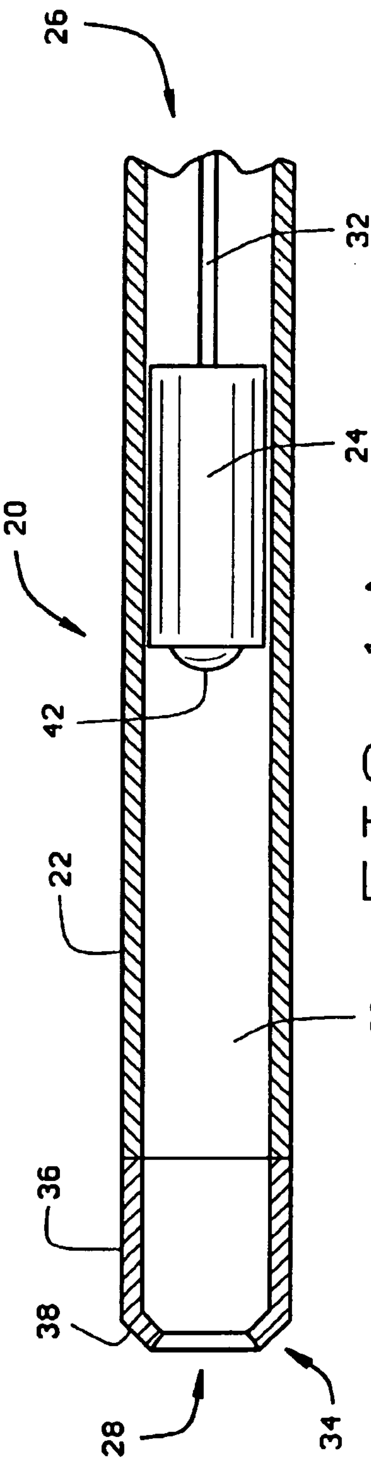


FIG. 1A

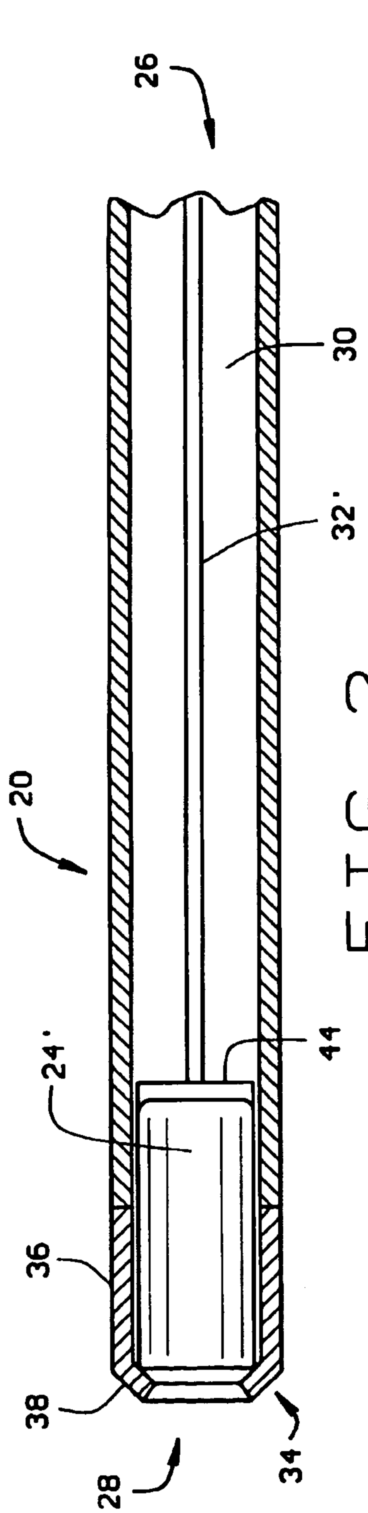

26
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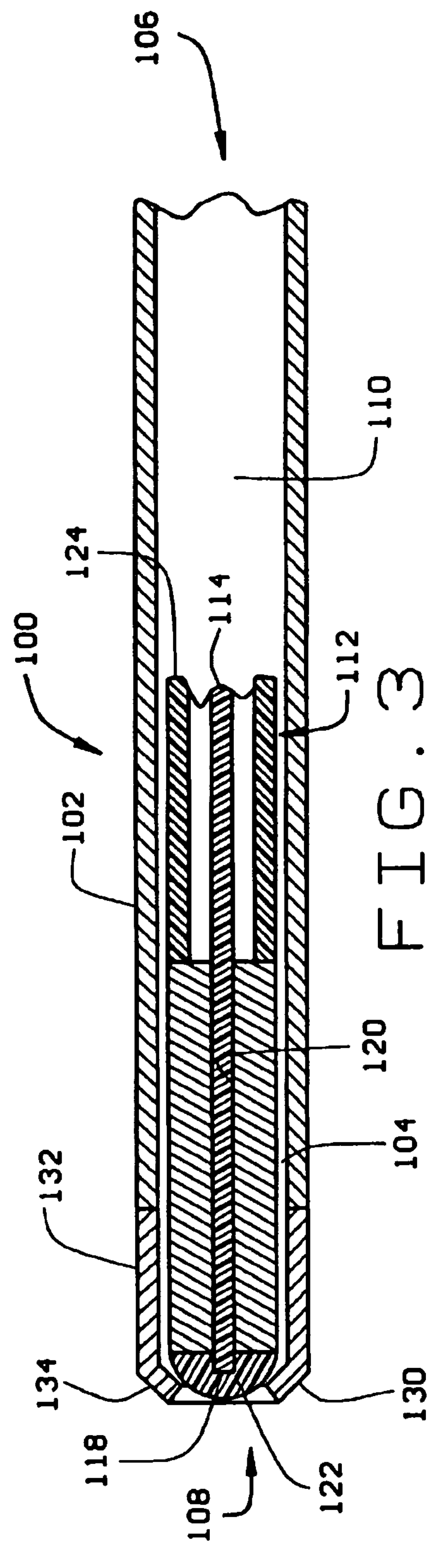
FIG. 2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100
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122
108

FIG. 3

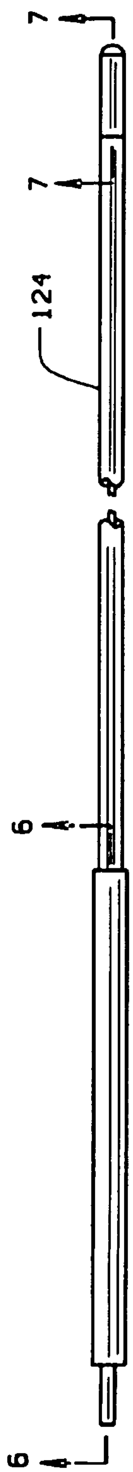

FIG. 4

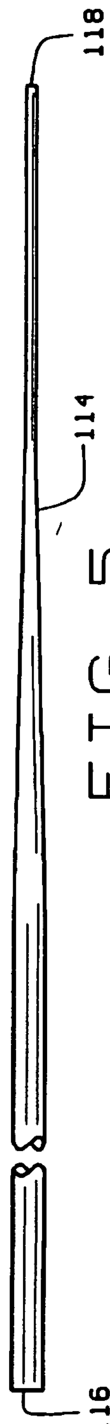

FIG. 5

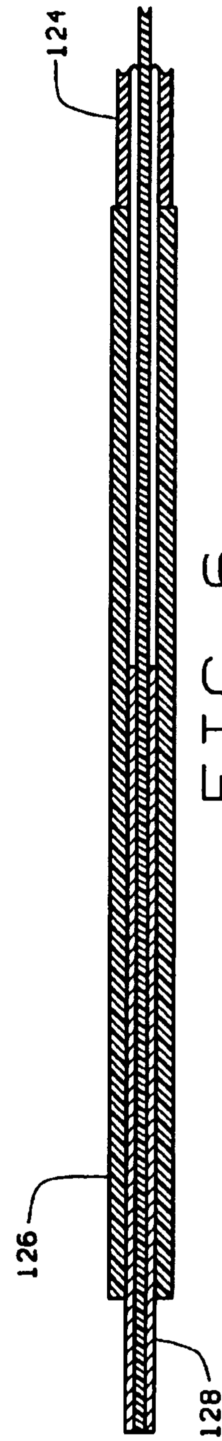

FIG. 6

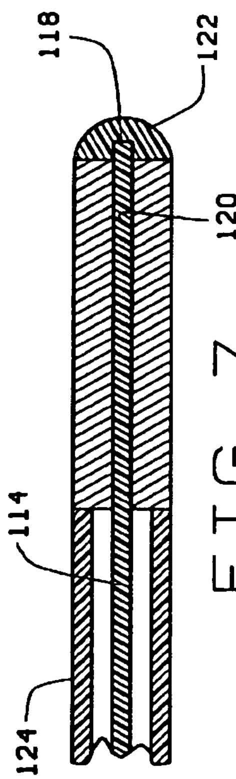

FIG. 7

METHOD OF AND APPARATUS FOR INTRAPARENCHYMAL POSITIONING OF MEDICAL DEVICES

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation in part of U.S. patent application Ser. No. 08/920,446, entitled Method for Magnetically controlling Motion Direction of a mechanically pushed catheter, filed Aug. 29, 1997, incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to a method of, and apparatus for positioning a medical device in the body through the tissue (intraparenchymally).

BACKGROUND OF THE INVENTION

Many diagnostic and therapeutic medical procedures require transporting a medical device through the body to a particular location. There are two principal routes through the body: through the body tissue (intraparenchymally) or through the blood vessels (intravascularly).

Several methods and apparatus have been developed for the intraparenchymal placement of medical devices in the body. One such method and apparatus, disclosed in Howard et al., U.S. Pat. No. 5,125,888, incorporated herein by reference, employs a magnet releasably attached to the medical device. The device is moved within the body by the controlled application of a magnetic field to the magnet. The magnetic field guides the magnet, which in turn guides the medical device to which it is attached. Once the medical device is in its desired position the magnet is released from the medical device and recovered, typically by manipulating it out of the body with a magnetic field.

While prior methods and apparatus which employed magnetism to position medical devices have numerous advantages, they also had some draw backs. First, recovery of the magnet could be difficult and time consuming, prolonging the medical procedure. Second, in some instances it can be difficult to generate a magnetic field sufficiently strong to move the medical device through the tissue, and in a desired strength and direction to move the medical device along the desired path.

SUMMARY OF THE INVENTION

The method and apparatus of the present invention involve magnetically guiding a medical device on an intraparenchymal path through the body. Generally according to the method of this invention a magnet is provided in the lumen of a catheter, adjacent the distal end with a tether extending from the magnet, through the lumen of the catheter to the proximal end. The distal end of the catheter has a restriction to retain the magnet in the lumen. The distal end of the catheter can be guided intraparenchymally to its desired position by the controlled application of a magnetic field, which acts on the magnet inside the lumen. Once the distal end of the catheter is in its desired position, the magnet can be quickly and easily withdrawn through the lumen of the catheter with the tether, eliminating the need to detach and manipulate the magnet out of the body encountered with some prior art methods.

Further, according to one embodiment of the invention, the tether can be sufficiently stiff to function as a guide wire to help advance the catheter through the tissue. In this embodiment, the magnetic field need only be sufficiently strong to freely orient the magnet inside the distal tip of the catheter, and the motive force for advancing the catheter through the tissue is provided by tether or guide wire. The distal end of the tether/guide wire is preferably relatively flexible to allow the magnet to freely orient the distal end of the catheter under the influence of an applied magnetic field. The proximal end of the tether/guide wire is preferably relatively stiff so that it can urge the distal end of the catheter through the tissue.

The method and the catheter/guide wire or catheter/tether of the present invention facilitate quick, easy and accurate intraparenchymal positioning of a catheter in the body. Once the catheter is properly positioned it can be used during a diagnostic or therapeutic procedure, either directly or as a passage for other medical devices.

These and other features and advantages will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal cross-sectional view of a first embodiment of a catheter and magnet combination constructed according to the principles of this invention;

FIG. 1A is a longitudinal cross-sectional view of the first embodiment with the magnet partially withdrawn from the distal end of the catheter;

FIG. 2 is a longitudinal cross-sectional view of an alternate construction of the first embodiment of a catheter and magnet combination;

FIG. 3 is a longitudinal cross-sectional view of a second embodiment of a catheter and magnet combination constructed according to the principles of this invention;

FIG. 4 is a top plan view of the magnet and attached tether/guide wire of the second embodiment;

FIG. 5 is a top plan view of guide wire core of the tether/guide wire shown in FIG. 4;

FIG. 6 is a vertical longitudinal partial cross-sectional view of the distal end of the tether/guide wire taken along the plane of line 6—6 in FIG. 4; and

FIG. 7 is a vertical, longitudinal partial cross-sectional view of the proximal end of the tether/guide wire taken along the plane of line 7—7 in FIG. 4.

Corresponding reference numbers indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A first embodiment of a catheter and magnet composition constructed according to the principles of this invention is indicated generally as 20 in FIG. 1. The catheter and magnet combination 20 comprises a catheter 22 and a magnet 24. The catheter 22 is of fairly conventional construction, having a proximal end 26, a distal end 28, and a lumen 30 extending therebetween. The catheter 22 can be made of polyurethane tubing, or some other suitable material. The size of the catheter 22 depends upon where in the body it will be introduced, and how it will be used. For use in the brain, the catheter might have an outside diameter of about 3.2 mm and an inside diameter of about 2.8 mm, and a length of about 14 cm.

The magnet 24 is preferably a NdFeB (neodymium-iron-boron) magnet sized to respond to the magnetic field that will be applied to move the catheter and magnet combination through the body. The magnet is sufficiently small to

pass through the lumen 30 of the catheter 22. The magnet is preferably elongated so that it can orient the distal tip of the catheter in the presence of an applied magnetic field. A tether 32 extends from the magnet 24 through the lumen 30 of the catheter 22. The tether 32 is preferably made of nitinol, which is highly flexible and resists kinking, although the tether could be made of some other suitable material.

The magnet 24 is preferably positioned inside the lumen 30, adjacent the distal end 28 of the catheter 22. The lumen 30 adjacent the distal end 28 of the catheter 22 preferably has a stricture 34 therein for retaining the magnet 24 in the lumen. In this preferred embodiment, the distal end 28 of the catheter 22 has a tip 36 with a tapering end 38 that forms the stricture 34. The tip 36 may be made of urethane coated tantalum.

With the magnet 24 in the lumen 30 of the catheter 22, the catheter 22 can be introduced into the body and guided to its desired position by the controlled application of magnetic fields. Once the distal end of the catheter 22 has been placed in its desired position, the magnet 24, which is proximal to the stricture 34, can be withdrawn from the lumen 30 by pulling the tether 32 (compare FIG. 1 and FIG. 1*a*).

As shown in FIGS. 1 and 1*a*, the magnet 24 has a axial bore therethrough and the tether 32 extends through the bore, terminating in a head 40 that secures the tether to the magnet. An alternative construction of the magnet and tether is shown in FIG. 2. As shown in FIG. 2, the magnet 24' is solid and the tether 32' has a seat 44 on its distal end for engaging the proximal end of the magnet 24'. The magnet 24' can be adhesively held in the seat 44, or the seat can be crimped onto the proximal end of the magnet.

A second embodiment of a catheter and magnet composition constructed according to the principles of this invention is indicated generally as 100 in FIG. 3. The catheter and magnet combination 100 comprises a catheter 102 and a magnet 104. The catheter 102 is of fairly conventional construction, having a proximal end 106, a distal end 108, and a lumen 110 extending therebetween. The catheter 102 can be made of about polyurethane tubing, or some other suitable material. The size of the catheter 102 depends upon where in the body it will be introduced and how it will be used. For use in the brain, the catheter about might have an outside diameter of 3.2 mm and an inside diameter of about 2.8 mm, and a length of about 14 cm.

The magnet 104 is preferably a NdFeB (neodymium-iron-boron) magnet sized to respond to the magnetic field that will be applied to orient the catheter and magnet combination inside the body. The magnet 104 is sufficiently small to pass through the lumen 110 of the catheter 102. The magnet preferably has an elongate shape to allow the magnet to be oriented in an applied magnetic field. In this preferred embodiment, the magnet is a cylinder about 2.2 mm inches in diameter and about 0.6 cm long. The magnet may be encapsulated in a urethane coating.

A tether 112 extends from the magnet 104 through the lumen 110 of the catheter 102. In the preferred embodiment, the overall length of the tether is about 51.2 inches (130 cm). The tether comprises a core guide wire 114, which is preferably made of nitinol. The guide wire 114 has a proximal end 116 and a distal end 118 (see FIG. 5). As shown in FIG. 5, the guide wire 114 tapers toward the distal end 118, so that the distal end of the guide wire is more flexible than the proximal end. In this preferred embodiment the guide wire 114 has a diameter of 0.033 inches (0.084 cm) and tapers over the distal 3.9 inches (10 cm) to a diameter of about 0.011 inches (0.028 cm).

The distal end 118 of the guide wire 114 extends through an axial bore 120 in the magnet 104. A cap of epoxy 122 secures the magnet 104 to the guide wire 114.

The distal portion of the guide wire 114 is covered with a sheath 124, made of flexible polyurethane tubing. The sheath 124 preferably has the same outside diameter as the magnet 104, to smoothly slide in the lumen 110, and to help prevent the excessive movement of the tether within the lumen. In this preferred embodiment the sheath 124 is about 36 inches (91 cm) long. The sheath 124 is preferably secured to the proximal end of the magnet 104 with an adhesive, such as SICOMET 40 FDA approved epoxy, available from Tracon. The proximal portion of the guide wire is covered with a sheath 126 made of braided polyethylene tubing. In this preferred embodiment, the sheath 126 is about 13.5 inches (34.3 cm) long. A metal cannula 128 (see FIG. 6) covers the proximal portion of the wire, and extends partly under the sheath 128. In this preferred embodiment, the cannula 128 extends proximally of the sheath 126 about 1.1 inches (2.8 cm). The sheath 126 and the metal cannula 128 help stiffen the proximal portion of the tether 112 so that the tether can be used to push the catheter, into which it is inserted, through the tissues of the body.

The magnet 104 is preferably positioned inside the lumen 110, adjacent the distal end 108 of the catheter 102. The lumen 110 adjacent the distal end 108 of the catheter 102 preferably has a stricture 130 therein for retaining the magnet 104 in the lumen. In this preferred embodiment, the distal end 108 of the catheter 102 has a tip 132 with a tapering end 134 that forms the stricture 130. The tip 132 may be made of urethane coated tantalum.

With the magnet 104 in the lumen 110 of the catheter 102, and the tether 112 extending through the lumen and out the distal end, the catheter 102 can be introduced into the body. The distal end of the tether 112 is highly flexible, and thus the magnet 104 inside the lumen can be oriented by the controlled application of magnetic fields, so that the distal end of the catheter 102 can be pointed in a particular direction. Once the distal end 108 of the catheter 102 is pointing in the desired direction, the catheter can be advanced in that direction by pushing the proximal end of the tether 112, which pushes the catheter. The distal end 108 of the catheter 102 can be reoriented, by changing the magnetic field to reorient the magnet 104, and the catheter advanced by pushing on the proximal end of the tether 112.

Once the distal end 108 of the catheter 22 has been placed in its desired position, the magnet 104, which is proximal to the stricture, can be withdrawn from the lumen 110 by pulling the tether 112. The catheter 102 can than be used directly for a diagnostic or therapeutic medical procedure, or the catheter can be used as a passageway for other medical devices to perform a diagnostic or therapeutic medical procedure.

Operation

In operation, the catheter and magnet combination 20 is introduced through an opening in the body. A magnetic field is applied to orient and advance the catheter and magnet combination through the tissue to the desired position. Once the distal end 28 of the catheter is in its desired position, the magnet 24 is removed from the catheter 22 by pulling the tether 32 to withdraw the magnet through the lumen 30 of the catheter.

In operation, the catheter and magnet combination 100 is introduced through an opening in the body. A magnetic field is applied to orient the magnet 104 in the distal end 108 of the catheter 102, and the catheter is advanced in the direction that the tip is pointing by pushing the tether 112. Once the

distal end 28 of the catheter is in its desired position, the magnet 104 is removed from the catheter 102 by pulling the tether 112 to withdraw the magnet though the lumen 110 of the catheter.

Once the catheter 22 or 102 is in position it can be used to perform a medical procedure or it can be used as a guide to insert medical devices to the area surrounding the distal end of the catheter to perform a medical procedure.

What is claimed:

1. In combination with a catheter having a proximal and distal end and a lumen therebetween, a magnet in the distal end of the lumen so that the distal end of the catheter can be positioned within the body with the aid of an externally applied magnetic field, and a tether attached to the magnet and extending through the lumen and out the proximal end so that the magnet can be removed from the catheter through the lumen once the distal end of the catheter is properly positioned.

2. The combination according to claim 1 wherein the distal end of the lumen has a stricture for preventing the magnet from exiting through the distal end of the catheter.

3. A method of positioning the distal end of a catheter within the body, the method comprising:

placing a magnet inside the lumen of the catheter adjacent the distal end, the magnet having a tether extending through the lumen and out the proximal end;

inserting the distal end of the catheter into the body;

applying a magnetic field to the distal end of the catheter to help guide the distal end of the catheter to the desired position within the body;

pulling the tether to withdraw the magnet from the lumen of the catheter once the distal end of the catheter is properly positioned.

4. A method of positioning the distal end of a catheter within the body, the method comprising:

inserting a guide wire having a magnet on its distal end into the lumen of the catheter until the magnet is adjacent the distal end of the catheter;

inserting the catheter into the body;

moving the distal end of the catheter to the desired position within the body by applying a magnetic field to the magnet in the distal end of the catheter to orient the distal end of the catheter in the desired direction of travel, and advancing the catheter in the desired direction by advancing the guide wire.

5. A method of positioning the distal end of a catheter within the body, the method comprising the step of inserting into the body the distal end of a catheter, having a guide wire with a magnet on its distal end in the lumen with the magnet adjacent the distal end, and moving the distal end of the catheter to the desired position within the body by applying a magnetic field to the magnet in the distal end of the catheter to orient the distal end of the catheter in the desired direction of travel, and advancing the catheter in the desired direction by advancing the guide wire.

6. A method of positioning the distal end of a catheter within the body, the method comprising the step of inserting into the body the distal end of a catheter having a magnet in the lumen adjacent the distal end; moving the distal end of the catheter to its desired position in the body by applying a magnetic field to the magnet in the catheter, and removing the magnet through the lumen of the catheter.

7. A method of positioning the distal end of a catheter within the body, the method comprising the step of inserting into the body the distal end of a catheter having a magnet in the lumen adjacent the distal end; moving the distal end of the catheter to its desired position in the body by applying a magnetic field to the magnet in the catheter to orient the distal end of the catheter; and advancing the catheter with a guide wire extending through the lumen of the catheter.

8. A guide wire adapted to be inserted into the lumen of a catheter to position the distal end of the catheter within the body, the guide wire having a proximal end and a distal end, the guide wire being more flexible adjacent the distal end than the proximal end, and a magnet on the distal end so that when the guide wire is in the lumen of a catheter, the magnet is adjacent the distal end of the catheter, the distal portion of the guide wire being sufficiently flexible to allow the magnet to move in response to a magnetic field to orient the distal tip of the catheter, and the proximal portion of the guide wire being sufficiently stiff to allow the guide wire to push the catheter through the body.

9. A catheter for being magnetically guided as it is advanced through an opening in a patient's body, said catheter comprising a magnetic tip positioned near a distal end of the catheter, and a tether attached to the magnet to permit withdrawal of the magnetic tip after the catheter has been desirably positioned.

10. The catheter of claim 9 wherein the magnetic tip is slidably received with the catheter and wherein the catheter has a structure preventing the magnetic tip from being driven out of the distal end of the catheter.

11. The catheter of claim 10 wherein the tether comprises a wire extending through the catheter and attached to the magnetic tip.

12. The catheter of claim 11 wherein the catheter comprises a lumen, and wherein the magnetic tip is sized to slide within the lumen, and wherein the structure comprises a taper at the distal end of the lumen to thereby physically prohibit the exit of the magnetic tip out of the distal end.

13. The catheter of claim 12 wherein the magnetic tip further includes an axial bore through which the tether extends and the tether further comprises a head secured to its distal end and which has a radial dimension large enough to prevent its being drawn throughout the axial bore so that as the head is positioned distal to the magnetic tip, the head contacts it to pull it out of the catheter as the tether is withdrawn therefrom.

14. The catheter of claim 13 further comprises a sheath surrounding the tether and having approximately the same cross section as the magnetic tip so that both the magnetic tip and the tether slide smoothly within the catheter.

15. The catheter of claim 14 further comprising a second sheath and rigid cannula surrounding a proximal end of the tether, the second sheath abutting the first sheath and the rigid cannula being positioned within the second sheath.

16. The catheter of claim 12 wherein the tether further comprises a seat on its distal end for engaging the proximal end of the magnetic tip and for being attached thereto.

17. The catheter of claim 16 further comprising a sheath surrounding the tether and having approximately the same cross section as the magnetic tip so that both the magnetic tip and the tether slide smoothly within the catheter.

18. The catheter of claim 17 further comprising a second sheath and rigid cannula surrounding a proximal end of the tether, the second sheath abutting the first sheath and the rigid cannula being positioned within the second sheath.

* * * * *

United States Patent [19]
Anderson

[11] 4,244,362
[45] Jan. 13, 1981

[54] ENDOTRACHEAL TUBE CONTROL DEVICE

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[21] Appl. No.: 964,503

[22] Filed: Nov. 29, 1978

[51] Int. Cl.³ A61M 25/00; A61M 16/00
[52] U.S. Cl. 128/200.26; 128/1.3; 128/207.14; 128/772; 128/DIG. 9
[58] Field of Search 128/1.3, 1.4, 772, 348-351, 128/DIG. 9, 200.26, 207.14

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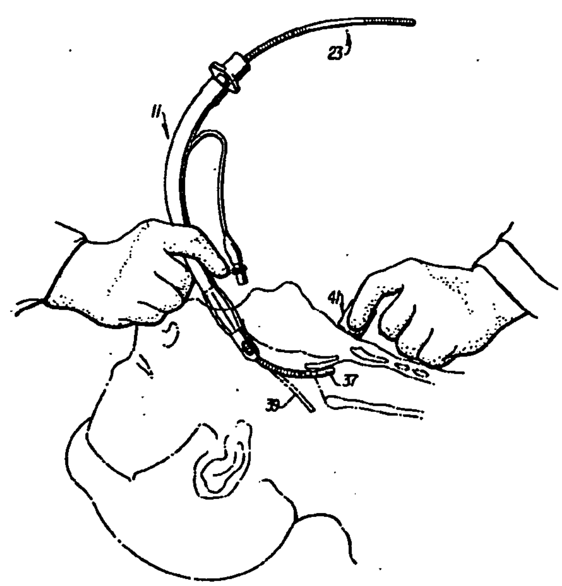
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—John E. Benoit

[57] ABSTRACT

An endotracheal intubation control device is disclosed which is used with a flexible tube that is tapered for insertion into the trachea of a patient. A stylet is provided having a length greater than the tubular member and of a dimension allowing passage through the member with first magnetic means attached to one end of the stylet. A second magnetic means is provided for external placement over the tracheal orifice of a patient. The stylet is flexible and is inserted into the throat of the patient and acts as a guide for subsequent insertion of the endotracheal tube over the stylet.

7 Claims, 11 Drawing Figures



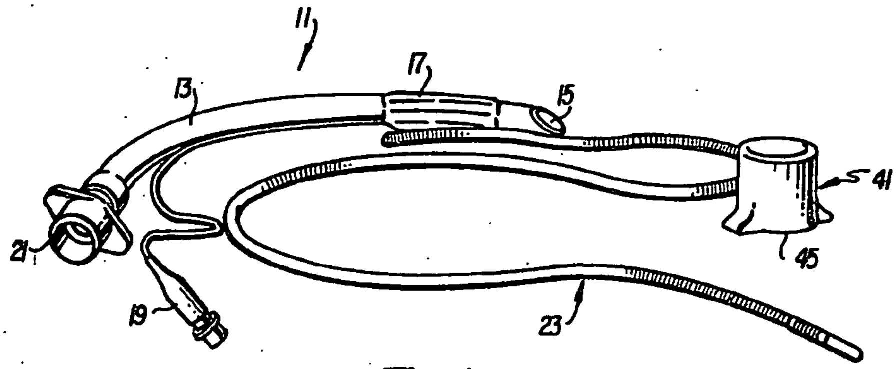
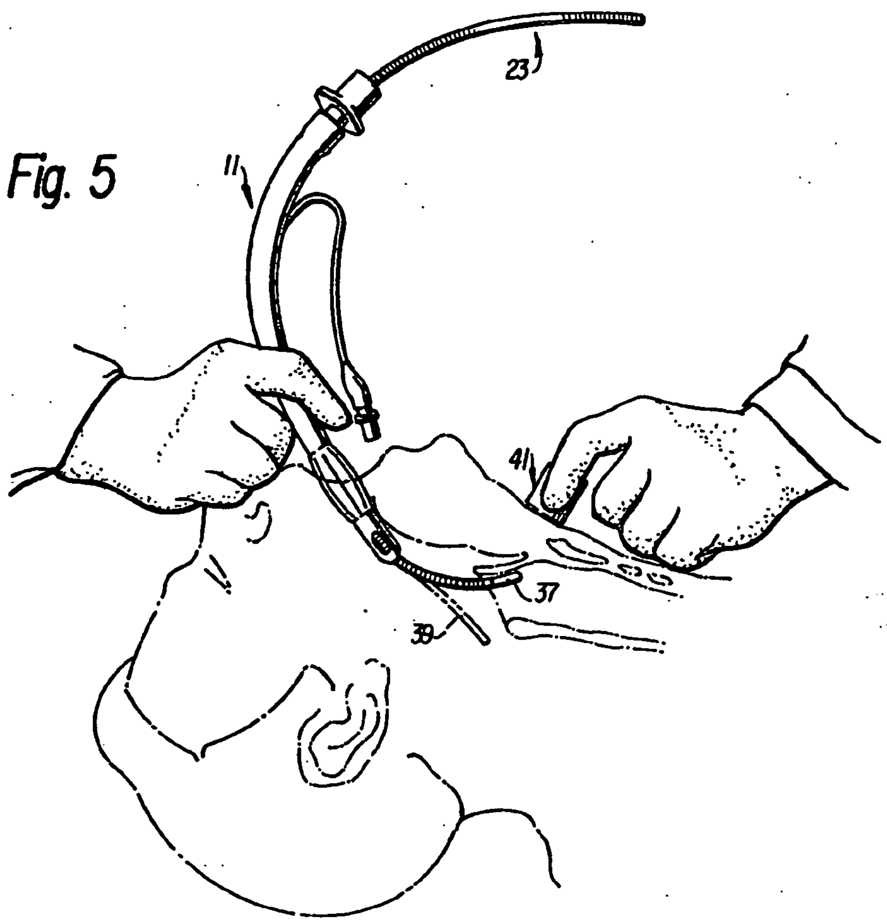


Fig. 1

Fig. 5



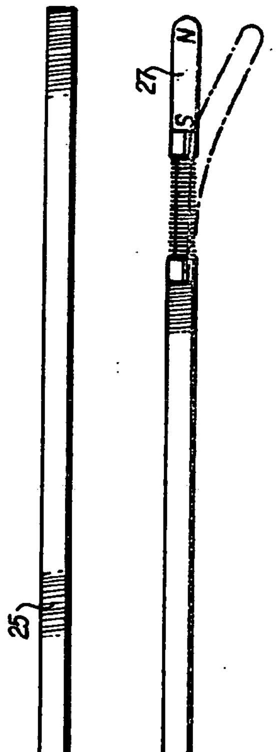


Fig. 2

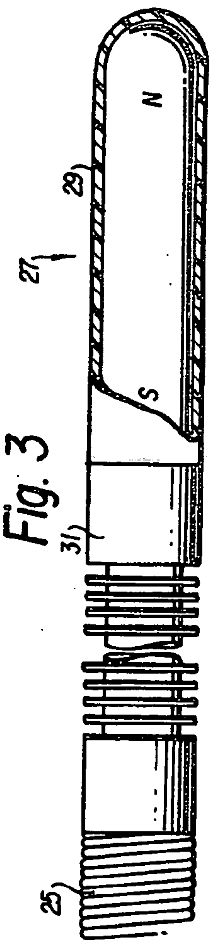


Fig. 3

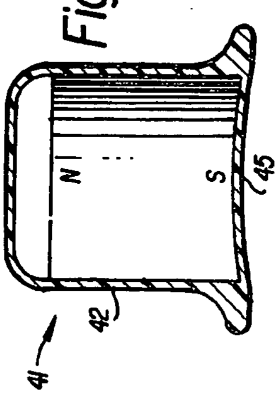


Fig. 4

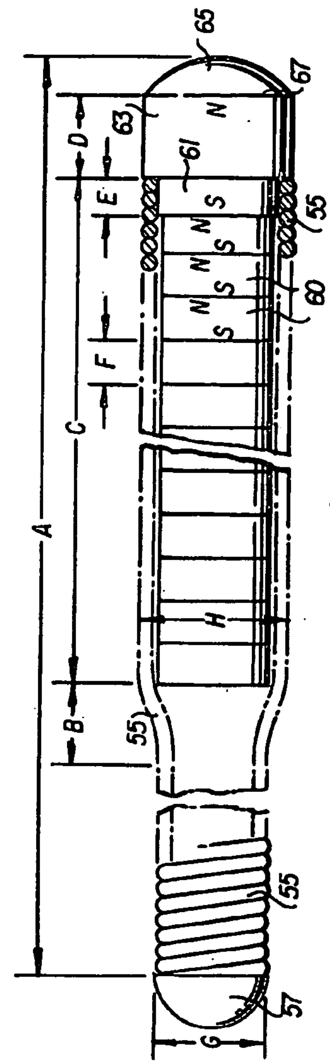


Fig. 10

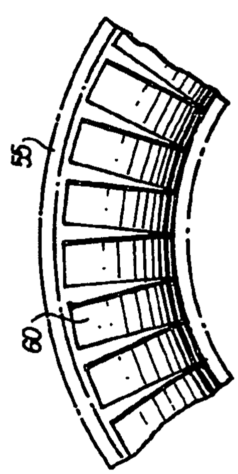


Fig. 11

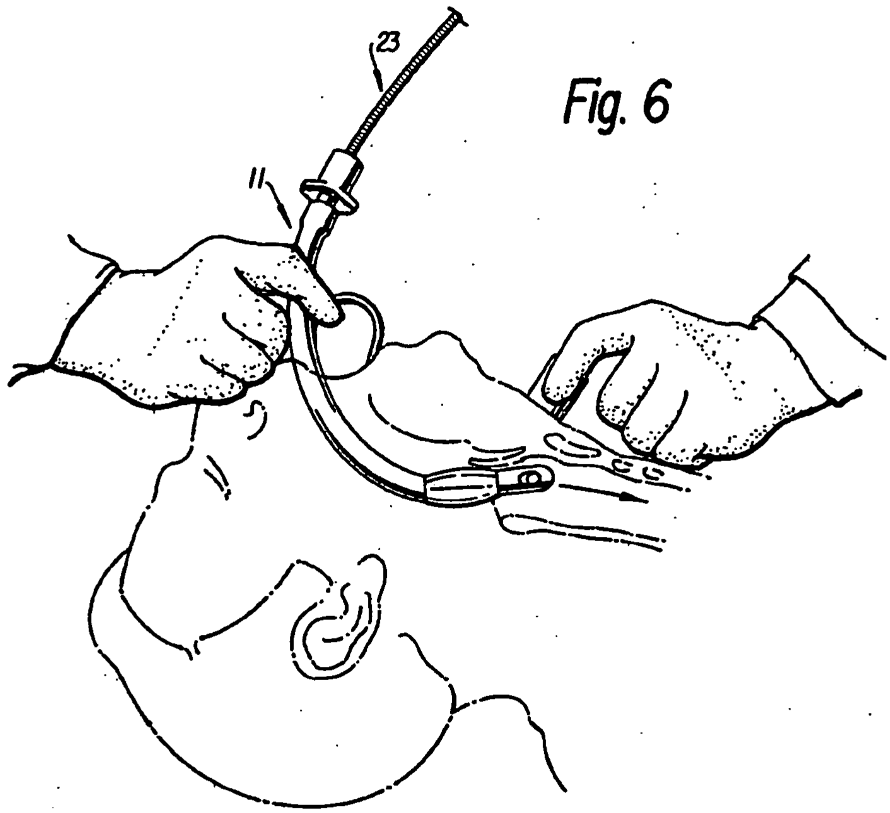


Fig. 6

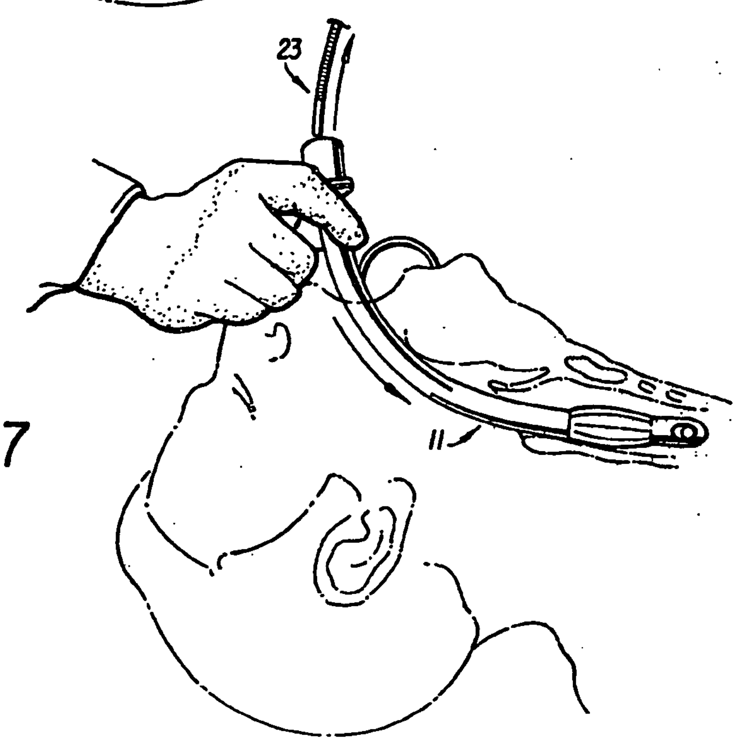


Fig. 7

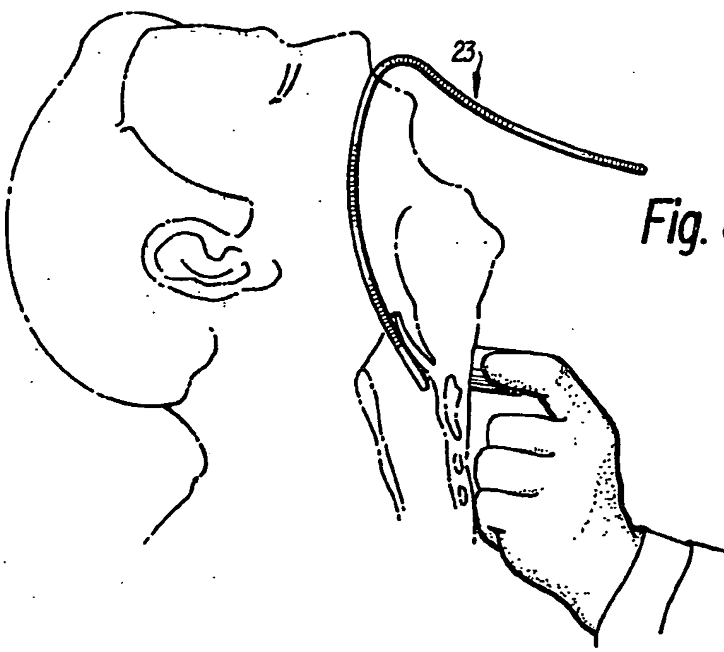
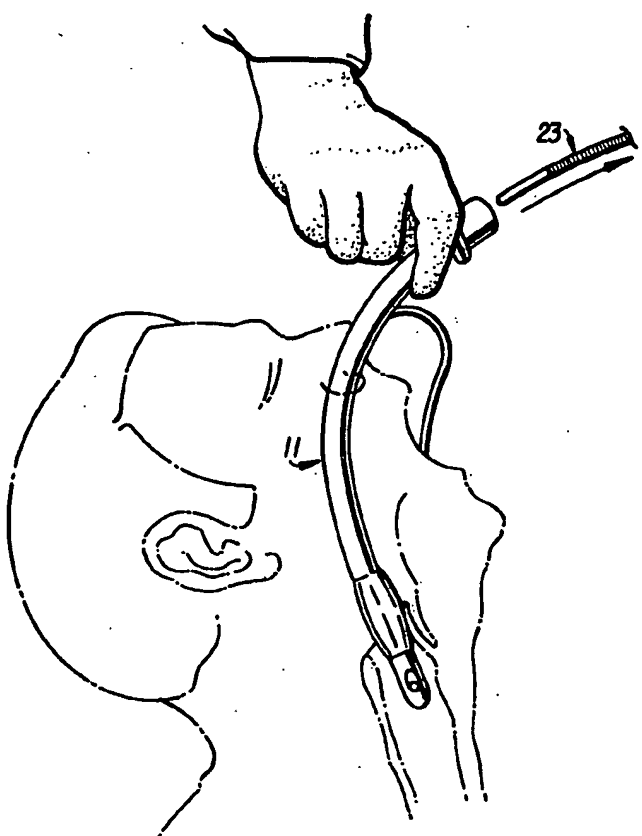


Fig. 8

Fig. 9



ENDOTRACHEAL TUBE CONTROL DEVICE

The present invention relates generally to an endotracheal tube control device, and more specifically to a magnetically controllable stylet for assisting in the insertion of an endotracheal tube.

BACKGROUND OF THE INVENTION

In a number of medical circumstances including routine surgery and intensive care, spontaneous respiratory capability is diminished, and a breathing assist is required. This breathing assist involves the forcing of air into the lungs by positive pressure. Positive pressure ventilation is supplied by a small bag of air or oxygen mixture squeezed by an anesthesiologist or by a bellows or piston in a mechanical ventilator. To insure that the air actually goes into the lungs rather than the esophagus and stomach and to insure that an open airway is always present during surgery or mechanical ventilation in the intensive care unit, a tube is inserted into the trachea such that the distal tip is well below the vocal cords. This tube, called an endotracheal tube, may be inserted through the mouth or the nose but must bend anteriorly in the throat in order to enter the trachea and avoid the esophagus. Once the tube is in place in the trachea, a circumferential balloon-cuff above the distal tip of the endotracheal tube is inflated with air. This balloon-cuff seals the tube in the trachea by filling the area between the tracheal wall and the endotracheal tube. Such an arrangement allows positive pressure to be applied and the lungs inflated by the anesthesiologist or mechanical ventilator. The balloon-cuff also protects the trachea from any foreign material from the mouth or regurgitated from the stomach.

Ever since the endotracheal tubes were introduced, anesthesiologists and other physicians have experienced difficulties placing endotracheal tubes into the trachea, a procedure called intubation. Of all procedures done in the intensive care unit related to maintaining ventilation of critically ill patients, intubation of the trachea is associated with the greatest number of complications. Very few physicians other than anesthesiologists have any proficiency at inserting endotracheal tubes. Usually, intubation involves the use of a device called a laryngoscope.

In order to insure that the endotracheal tube goes into the airway to trachea instead of the esophagus, the anesthesiologist must visualize the vocal cords by extending the patients head slightly and by elevating the jaw of the patient with the laryngoscope. In his position behind the patient's head, he can place the tube between the vocal cords, into the trachea below. One of the principle dangers of this procedure is that it almost always requires that the patient be temporarily paralyzed. Paralysis of the patient facilitates visualization of the vocal cords by relaxing the jaw muscles and preventing the patient from retching or otherwise interfering with the placement of a large piece of metal (the laryngoscope) down his throat. Unfortunately it also eliminates any contribution that the patient might take towards his own breathing. Failure to place the endotracheal tube rapidly can result in death if the patient cannot be ventilated by a mask placed tightly over his mouth and nose in between attempts to intubate with the laryngoscope. Ventilating a patient by mask and positive pressure from a bag of oxygen also requires

particular skill and practice and is nearly impossible with some patients and without proper equipment.

Even experienced anesthesiologists have difficulty intubating certain patients. Patients with the following problems are particularly difficult to intubate:

(1) short muscular neck
(2) receding jaw
(3) large, thickened tongue
(4) high arched palate
(5) cleft lip or palate
(6) cervical or temperomandibular arthritis (common in elderly patients, prevents adequate extention of the neck in order to see the vocal cords)
(7) post surgical scars or burns to the face, neck, or mouth
(8) pharngeal or laryngeal tumors
(9) inflammation of the epiglottis or tonsils
(10) facial fractures
(11) thyroid disease (colloid, goiter, substernal thyroid)
(12) deviation of the epiglottis, vocal cords, or trachea from the midline by stricture or kyphoscoliosis.

Such patients are difficult to intubate under the best of circumstances, that is, in the operating room prior to elective surgery. At this time the anesthesiologist has time and appropriate equipment and other skilled persons to give the patient 100% oxygen prior to putting him to sleep and paralyzing him. The patient can be properly positioned and counseled to know what to expect. Even if his intubation is prolonged and difficult, he is put to sleep first by intravenous medication and is not aware of the complication. Intubating patients in the intensive care unit, emergency room, coronary care unit, or elsewhere outside the operating room is much more difficult. Unlike the well-prepared, sedated, and pre-oxygenated patient on the operating room table, the intensive care patient or emergency room patient is often in great respiratory and cardiovascular distress at the time endotracheal intubation is mandatory. He may be so short of breath that he refuses to lie down or allow a tight fitting mask on his face. Time and skill are of great importance, as is experience obviously, to overcome unexpected anatomic problems in choking, suffocating, uncooperative, frightened patients. Some types of lung disease leave the lungs so stiff that adequate ventilation with a mask is not possible. Since the patient is already in respiratory distress despite the usual administration of oxygen by a loosely fitted mask, the rapid institution of an intravenous sedative and paralyzer is a gamble that an endotracheal tube can be inserted swiftly in spite of unexpected anatomical problems which could interfere with intubation, and should intubation not be successful, that an appropriate mask, oxygen source, anesthesia bag, and skill are at hand to ventilate the paralyzed patient in between intubation attempts or until more skilled persons and/or equipment are available. Should the endotracheal tube be inadvertently placed in the esophagus, the forcing of air into the esophagus can result in rupture of the stomach or, more commonly, the inducement of vomiting. Gastric contents may then go into the airway and severely damage the lungs.

Skill with a laryngoscope only comes with constant practice. It is therefore not surprising that only anesthesiologists and certain intensive care physicians are capable of intubating the trachea proficiently. On occasion, an endotracheal tube can be inserted into the nose and

blindly advanced into the throat and through the vocal cords without paralyzing the patient. This technique is particularly useful in the patient with acute respiratory distress because it requires only local anesthesia to the nose and allows the patient to continue with his own breathing, although it is not totally adequate for him, during the insertion of the endotracheal tube. Obviously, this blind technique requires even more skill and practice to avoid inserting the tube into the esophagus or injuring the patient. In addition, this nasal approach is often impossible for anatomic reasons even if an experienced person is making the attempt.

These problems have been discussed in part and a proposed device disclosed in U.S. Pat. No. 4,063,561 issued Dec. 20, 1977. The device disclosed therein is a newly constructed endotracheal tube which includes therein metallic material within the walls of the tube and which may be affected by external magnetic devices placed over the larynx of the patient externally. Obviously, the cost of manufacturing individual tubes with metallic wire in the walls would be much greater than the cost of manufacturing the present invention, which can be used with any existing endotracheal tube, is reusable indefinitely, and has no expensive parts.

The above mentioned patent further discloses a possibility of enclosing frictionally a metallic block within the tube lumen which is secured to the end of a flexible wire whereby an ordinary endotracheal tube can be inserted into the throat and the entire tube manipulated by an external magnet into the trachea. All endotracheal tubes must be stiff enough to prevent excessive collapse when they bend. For this reason, normal endotracheal tubes cannot be manipulated externally with a necessarily small piece of metal within the lumen of the tube. Such an arrangement could be potentially dangerous. The block of metal could become dislodged from the wire and drop into the trachea. Further, such a metallic plug may become stuck upon its withdrawal at the point of anterior bend of the endotracheal tube in the nose or mouth, completely occluding the airway. The problems arising from this arrangement are further apparent from the fact that the emphasis in the above mentioned patent is upon the creation of a new endotracheal tube. The attraction of a magnet, no matter how large, for a piece of metal is still a function of the mass of both pieces of metal. The size of the metallic plug as illustrated in the patent cannot be large enough to manipulate a normal endotracheal tube because it must fit into the lumen of the tube. Increasing the size of the magnet outside will not overcome the distances involved or the stiffness of the ordinary tube.

The above disadvantages are overcome by the present invention wherein a very flexible stylet, instead of a whole endotracheal tube, is controlled by an external magnet by incorporating a second magnet into the distal end of the stylet. This small magnet on the distal tip of the stylet has opposite polarity to the external magnet, thus increasing their attraction and providing consistant alignment and direction toward the vocal cords. The stylet may be inserted through the mouth or nose in almost any body position and is of a dimension of fit within a standard endotracheal tube without completely occluding its lumen. After the distal tip of the stylet is within the trachea, the endotracheal tube is advanced over the stylet into the trachea, and the stylet quickly removed. Accordingly, it can be seen that the stylet acts as a flexible intubating guide for the endotracheal tube. To facilitate removal of the stylet from the endotracheal tube, the diameter of the stylet is much smaller than the lumen of the endotracheal tube. The magnet at the tip of the stylet may be constructed out of many small magnets. When stuck together, they function exactly like one long magnet, but when bent around a tight turn will articulate with one another and allow flexibility and easy withdrawal once the endotracheal tube has been advanced over the stylet into the trachea. This arrangement of many small articulating magnets functioning as one magnet is especially useful as the size of the endotracheal tube decreases. Larger endotracheal tubes do not require the articulation of small magnets at the distal tip of the stylet because there is adequate space in the lumen to withdraw the stylet without the magnet becoming lodged in the tube at its point of bend in the posterior pharynx. The flexible stylet may be inserted originally into the mouth or nose and directed into the trachea before the endotracheal tube is advanced over it, or the stylet and endotracheal tube may be advanced as a unit or alternately, as long as the stylet stays several inches in front of the tip of the endotracheal tube. In any case, once the tube has been advanced into the trachea, the stylet is quickly removed, the balloon-cuff of the tube inflated, and positive pressure ventilation initiated. Paralysis is never necessary. Local anesthetic agents may be sprayed or applied to the nose, throat, and tongue prior to insertion of the stylet. Mild sedation may be given, but the patient continues to breathe for himself and may remain in the sitting position if he desires.

Besides a system of nasal or oral tracheal intubation, the stylet is constructed to be not only very flexible and responsive to the external magnet but also to be at least twice the length of a standard endotracheal tube. This extra length provides the ability to change one endotracheal tube that may be defective or too small with a new endotracheal tube, again without paralysis or a laryngoscope. In this case the stylet is inserted (using the end opposite the magnetic tip) into the old endotracheal tube and the old tube removed when the stylet is in the trachea. Then a new tube can be advanced over the stylet and the stylet withdrawn. This procedure is rapid, does not require an external magnet, and is far safer and easier than removing the old tube and necessitating the insertion of a new tube by sedation, paralysis, and a laryngoscope. The stylet is constructed of a material which is spring-like and slides easily inside the endotracheal tube, bends easily but can be pushed, confers enough rigidity to allow guidance for an endotracheal tube, but is very responsive in a magnetic field.

Accordingly, it is the purpose of this invention to provide an endotracheal tube insertion system which does not require the risky technique of paralysis, can be used by anesthesiologists to intubate patients with difficult anatomical problems through the nose or mouth, can be used by relatively unskilled medical personnel in emergencies when an anesthesiologist is not present, can be used in a variety of positions, including supine, sitting and lateral decubitus, and can be used and reused indefinitely on standard endotracheal tubes. This endotracheal tube insertion system provides for a flexible stylet, having a magnet attached to one end, to be guided into the trachea by means of an external magnet with opposite polarity. The endotracheal tube is advanced over the stylet so as to enter the trachea with the subsequent removal of the stylet.

It is a further object of this invention to provide a stylet guiding means which may be used to quickly

replace one endotracheal tube for another without paralysis or the use of a laryngoscope.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects of the invention will become apparent from the following description when taken in conjunction with the drawings wherein.

FIG. 1 is a perspective view of the three components preferably used with the present invention;

FIG. 2 is a perspective view of one embodiment of the stylet of the present invention;

FIG. 3 is an enlarged view of a section of the stylet of FIG. 2;

FIG. 4 is a sectional view of one embodiment of the external magnet used with the stylet of the present invention;

FIGS. 5, 6 and 7 illustrate the steps which are taken in using the present device for performing intubation orally;

FIGS. 8 and 9 show like steps which are taken when the insertion is through the nostril;

FIG. 10 is a sectional view of a further embodiment of the stylet of the present invention; and

FIG. 11 shows the interaction between individual magnets used in the stylet of FIG. 10.

Before proceeding with the description of the invention, reference should be made to the term "stylet" as used in the medical profession. A definition and a discussion of a stylet may be found in "Understanding Anesthesia Equipment" pages 274 and 275 authored by Jerry A. Dorsch, M.D. and Susan E. Dorsch, M.D., The Williams and Wilkins Company. In that discussion, it is stated that a stylet is a device which fits inside an endotracheal tube. It aides in directing the insertion of the tube by making the tube more rigid and allowing its shape to be changed. In the present invention, a stylet is used as herein indicated in that it is a device that fits inside an endotracheal tube and is used to help direct the tube. However, as defined herein, it is not designed to make the tube more rigid nor to change the shape of the tube. Accordingly, for the present purposes a stylet is defined as a flexible device which fits within a tube and may be passed therethrough. More specifically, the stylet of the present invention involves a flexible device having a magnet located at one end thereof. The stylet is springlike and is so constructed that it bends easily but can be pushed along its length.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

Turning now more particularly to the drawings, there is shown in FIG. 1 the three items which may be used in performing an intubation of the trachea using the stylet of the present invention. As illustrated, a standard endotracheal tube 11 comprising a plastic tube body 13 has a beveled insertion end 15 and an inflatable balloon 17. The balloon is inflated in a standard manner by the inflating syringe 19. The opposite end of the tube 13 terminates in a connector which may be secured to a breathing assist system. This is all known equipment used in the standard procedure as described hereinabove. The present invention provides a stylet 23, which will be more specifically shown and described as the description proceeds, and an exterior magnet 41. Magnet 41 is preferrably a housing of plastic material 43 having a magnet secured therein with one end having a concave face 45.

Turning now more specifically to FIG. 2, there is illustrated one embodiment of a stylet of the present invention. This stylet is most useful with endotracheal tubes having an internal diameter larger than 8.0 mm.

The main body 25 of the stylet is comprised of a coiled spring of a non-magnetic material such as stainless steel or other non-magnetic material. Such a tube could be constructed of a suitable plastic material manufactured so as to conform to the characteristics of a coiled spring. A magnet 27 is secured to the other end of the spring. Magnet 27 may be encased within an inert housing 29 (FIG. 3) such as stainless steel, plastic etc., which is then secured to one end of stylet 25 by means of a weld or adhesive or the like.

FIG. 3 is an enlarged partial illustration indicating the spring bellows 31 which is secured between the housing 29 and the body 25 of the stylet. Such bellows are commercially available and provide additional flexibility at the distal end of the stylet. This further aids the ability of the distal end to bend as shown in the dotted lines of FIG. 2 when it is subjected to exterior magnetic forces.

FIG. 4 shows one embodiment of exterior magnet 41. The magnet may be encased in an inert housing 42 of a material such as plastic or the like. As indicated, one face of housing 42 is concave for purposes which will become apparent as the description proceeds.

FIGS. 5, 6 and 7 illustrate the use of the device when intubation is practiced orally. FIG. 5 shows the stylet 23 being inserted with the magnetic end entering into the throat of the patient. When the stylet is so inserted, the end will assume a position approximately as shown in the dotted lines 39. If allowed to follow this course, the stylet will tend to enter the esophagus instead of the trachea. However, as indicated, the magnet 41 is placed exteriorly in the midline adjacent to the prominence of the thyroid cartilage, or "Adam's Apple". This is easily distinguishable on the patient and places the magnet in a proper spot for attracting the magnetized end of the stylet 37 into the tracheal passage as indicated in the solid line form. As shown in FIG. 6, the stylet is then inserted into the tracheal cavity by sliding it along inside the endotracheal tube. The tube is then guided along by the stylet as shown until it, too enters the tracheal passage. The stylet is then removed as shown in FIG. 7, leaving the endotracheal tube in position with the trachea.

FIGS. 8 and 9 illustrate that the same procedure may be used when the nostril is dilated and the stylet and the tube may then be inserted therethrough following the same procedure for locating the stylet and, subsequently, the endotracheal tube into position.

Turning more specifically to FIGS. 10 and 11, there is shown therein an alternate embodiment of the stylet of the present invention. The main body of the stylet is comprised of a similar coiled spring 55 which extends substantially the length of the stylet. A rounded cup 57 of an inert material such as teflon may be secured within one end of the coiled spring 55 by means of an adhesive or the like. The other end of coiled spring 55 has inserted therein a series of small magnets beginning with magnet 59 at one end and terminating at the other end with magnets 60 and 61. These magnets have a diameter slightly smaller than the internal diameter of the section of coil spring 55 which encases them. Spring 55 is made larger at this section to allow the magnets to interact as shown in FIG. 11. The magnets terminate in a larger magnet 63 which has a reduced section 61 which fits within the end of the coil spring and is secured thereto

by means such as by soldering or with an adhesive. Also, to provide a smooth insertion area, an inner hemispherical segment 65 is secured to the outer end of magnet 63 by means such as an adhesive. In order to present the stylet in an understandable dimensional view, the following parameters are typical of a desired stylet.

DIMENSION	PARAMETER-INCHES
A	27
B	¼
C	.8125
D	⅛
E	1/16
F	1/16
G	3/16 O.D.
H	¼ O.D.

FIG. 11 illustrates one of the reasons for providing the separate individual magnets as shown in FIG. 10. While the magnets do not totally part from each other because of the extreme force exerted between them, they may partially separate as illustrated in FIG. 11. This partial separation allows the terminal end of the stylet having the magnets to provide more flexibility and, thus, greater ease in drawing the stylets into the tracheal passage. This embodiment, when using the stylet with smaller diameter endotracheal tubes, allows the small magnets to function as one magnet, but articulate with each other, whereby the removal of the stylet from the smaller endotracheal tube is greatly eased. One of the reasons why this invention is now practical is due to the development of extremely high magnetic material such as cobalt and the like. This reduces the necessary size of the magnets while still realizing the necessary magnetic force, since the use of a magnetic material such as cobalt in the stylet itself increases the attraction between the exterior magnet and the end of the stylet to a very large degree. The use of only a metallic material for a stylet would reduce the ability to direct the end of the stylet into the trachea.

The above description and drawings are illustrative only since material substitution and dimension variations are possible without departing from the invention.

Accordingly, the invention is to be limited only by the scope of the following claims.

I claim:

1. An endotracheal intubation assembly comprising
a flexible intubating guide stylet;
first magnetic means attached to one end of said stylet and movable therewith;
an open ended flexible endotracheal tube having a lumen of a dimension substantially greater than the cross-sectional dimension of said stylet and said first magnetic means whereby said tube is freely movable over said stylet and said magnetic means, thereby permitting free flow of breathable gas along said lumen; and
second magnetic means externally placeable over the tracheal orifice of a patient;
whereby said one end of said stylet is inserted into the throat of said patient, with said first magnetic means being directed onto the trachea by said second magnetic means which is placed adjacent the external surface of said tracheal orifice area, and said endotracheal tube is threaded over said stylet and guided into the trachea by said stylet.

2. The device of claim 1 wherein said stylet comprises
a spring coil member having said first magnetic means secured to one end thereof.

3. The device of claim 1 further comprising
a spring bellows connected between said stylet and said first magnetic means.

4. The device of claim 2 further comprising
a spring bellows connected between said spring coil member and said first magnetic means.

5. The device of claim 1 wherein said stylet comprises a tubular plastic flexible member.

6. The device of claim 1 wherein said magnetic means comprises
a plurality of magnets having their poles arranged for adjacent magnetic attraction whereby articulation may occur between adjacent magnets.

7. The device of claim 1 further comprising
means providing a substantially smooth arcuate termination at the distal end of said first magnetic means.

* * * * *